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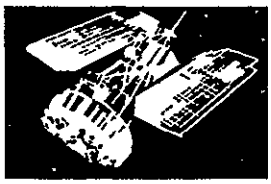
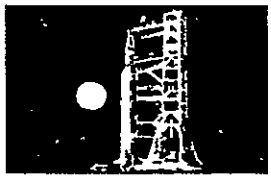
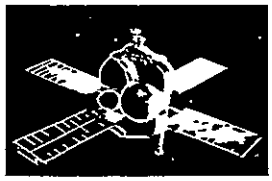

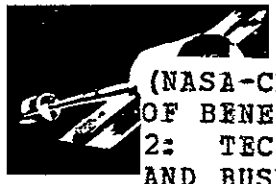
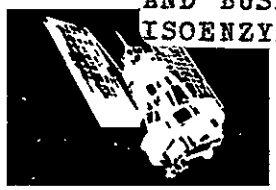
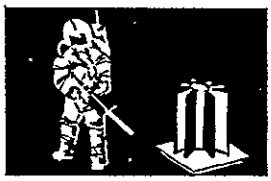
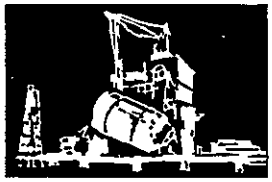

STUDY FOR IDENTIFICATION OF BENEFICIAL USES OF SPACE

(PHASE III)

FINAL REPORT

VOLUME II - TECHNICAL REPORT

BOOK 1 - DEVELOPMENT AND BUSINESS ANALYSIS OF SPACE PROCESSED ISOENZYMES

CONTRACT NAS8-28179

NOVEMBER 30, 1975

SUBMITTED PER DPD #451,

DR #MA-04

GENERAL ELECTRIC

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November 30, 1975

Submitted Per DPD #451, DR #MA-04

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PREFACE

The Final Report on Phase III of the Study for Identification of Beneficial Uses of Space (B. U. S.) is comprised of three volumes:

Volume I	Executive Summary
Volume II	Technical Report
Volume III	Appendices

Volume II is further subdivided:

Book 1 - Development and Business Analysis of Space Processed Isoenzymes

Book 2 - Development and Business Analysis of Space Processed Transparent Oxides

Book 3 - Development and Business Analysis of Space Processed Tungsten X-ray Targets

Book 4 - Development and Business Analysis of Space Processed Surface Acoustic Wave Devices

Book 5 - Study Methods and Trade Studies

General Electric's Space Division, under contract from the NASA's Marshall Space Flight Center completed Phase I of the Study in December 1972, and Phase II in December 1973. In Phase III, the Study has progressed to the Business Analysis and Planning for the commercial development and production of the four products in Phase II:

- Surface Acoustic Wave Components
- Transparent Oxides
- High Purity Tungsten X-ray Targets
- High Specificity Isoenzymes

The methodology employed in the Phase III Study and the results of that effort are reported herein.

In addition to Key Individuals from the participating User organizations who contributed specific product, process, business and planning data in each of their respective areas,

the Study Manager acknowledges the outstanding financial and manufacturing analysis contributions of Mr. P. Schmitt, and the considerable contributions of the following: Mr. U. Alvarado and Mr. M. Clarke of the Study Team in analyzing and organizing the wealth of data accumulated; Mr. K. Taylor, the MSFC Contracting Officers Representative (C.O.R.) for the study, in providing key technical suggestions and direction to the overall effort as well as establishing space processing payload guidelines, Mr. G. Wouch, Dr. E. Okress, and Dr. B. Noval of General Electric's Space Sciences Laboratory, in providing supporting space processing data, and Mr. B. Klawans and Mr. F. Curran of General Electric's Systems Operation and Computations Component in programming and processing "INVEST", the interactive profitability analysis program.

As noted in the Final Reports of earlier Phases, publication of this Phase III report neither implies NASA endorsement of any specific product, process or venture identified during this phase of the Study, nor a NASA commitment to pursue any program defined as part of this Study.

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SECTION I

INTRODUCTION

This volume comprises preliminary development plans, analysis of required R & D and production resources, the costs of such resources, and, finally, the potential profitability of a commercial space processing opportunity for electrophoretic separation of high specificity isoenzymes. The work reported herein is a continuation of investigations into the space processing of isoenzymes which have been conducted in Phases I and II of NASA Study Contract NAS 8-28179 (1971-1973).

Technical Support for these investigations has been provided by Polysciences, Inc. of Warrington, Pennsylvania, primarily by

Dr. B. Halpern, President

Dr. S. Ledis

Dr. S. Greenfield

The baselines selected for development planning are conceptual, and were established to provide a means of assessing overall technical and economic feasibility under conditions of limited experimental space processing information and very long range market, space facility, and cost projections. These baselines can be expected to change, perhaps even drastically, as later analytical and experimental investigations continue.

I.1 BACKGROUND

At present there are nearly 2000 identified enzymes, of which about 100 are known to have isoenzyme forms. Isoenzymes are alternate forms of enzymes (biological

catalysts) which exist in slightly different molecular forms. We have previously[1] noted the known, and possible, relationships of isoenzymes to certain diseases and organic damage, and the possibilities of utilizing high specificity separations of certain isoenzymes in the early diagnosis of some of these afflictions. However, the forces which stabilize the various structural levels of isoenzymes are extremely weak, and, during separation, are easily disturbed by heat, chemical agents, and strong electrical potentials, as can occur in conventional electrophoresis at high voltage gradients (~10 v/cm). These conditions cause distortion of the enzyme structure (denaturization), which results in the loss of enzyme activity. What is needed, therefore, is a "gentle" separation technique.

The most commonly and successfully employed ground-based isolation techniques for isoenzymes has been conventional small pore gel electrophoresis. Increased resolving power of separation, while maintaining low ohmic heating and low electrical potentials, is expected from proven techniques using large pore gels and/or isoelectric focusing in the "zero gravity" of orbital flight, where longer separation paths aid resolution and low voltage gradients minimize denaturization.

As pointed out in Reference 1, our goal in this area of Space Processing is the development of a separation method to provide reasonable yields of high specificity isoenzymes for the purpose of large scale, early clinical diagnosis of diseases and organic damage such as, possibly, myocardial infarction, hepatoma, muscular dystrophy, renal disease, nervous system disorders, cerebral infarction, other cancers, glycogen storage disease, and infectious disorders.

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[1] STUDY FOR IDENTIFICATION OF BENEFICIAL USES OF SPACE (PHASE I) NAS8-28179, Final Report, GE Document #73SD4259, December 10, 1972 and April 23, 1973.

I.2 ASSUMPTIONS

In addition to the basic Study Assumptions reviewed in Section IV of Volume I, the following key assumptions have been made in the development planning:

- The experiments and tests, defined in Phase II and updated in this Phase, will result in a successful technique for separating preparative amounts of higher specificity, undenatured isoenzymes through large-pore gel electrophoresis of enzymes in space. Other useful macromolecules will also be beneficially separable through use of the same techniques, and possibly, the same equipment model.

- Separated isoenzymes will be used primarily in diagnostic, as opposed to therapeutic, procedures, although the latter application may well offer even greater benefits in the future.

- An initial Study Guideline (Section IV.1, Volume I) directed that our profitability analysis assume that each User bear the full cost of developing the Space Process utilized for producing his product. All four of the products under study were unattractive ventures under the combination of this assumption and derived economic data. The NASA C.O.R. suggested that this combination be noted as "Case A".

  He further suggested that, since basic processes would have broader application than the individual products under study, it could likely be assumed that basic process proof-of-feasibility would be carried out under government funding. Users, therefore, would only bear those R&D costs that specifically provide prototype/pilot plant capability. The combination of this assumption and the same derived economic data as in the prior case is called "Case B".

I.3 PRODUCT OBJECTIVES

The primary product objective for isoenzymes is to utilize the "zero gravity" of the space environment to produce, via high specificity electrophoretic separation from sera, tissues, blood, etc., specific isoenzymes (which are present in disease or damage states) without denaturization.

The secondary product objective is to use the high specificity isoenzymes to create antibodies and market them to pharmaceutical companies, hospitals, clinics and physicians for use in diagnostic procedures. This objective requires the development of a process sufficient to deliver the high specificity isoenzyme products on a preparative scale (several thousand milligram annual throughput).

Isoenzymes of most immediate interest are creatine kinase and glycogen phosphorylase, although many others would be produced when, and if, the process becomes available.

I.4 PROCESS ALTERNATIVES AND BASELINE

The alternative process methods and key steps in the baseline approach selected for this Phase of Study have been derived in Phase II. These are shown in Figure I-1. Those major alternatives and decisions left unresolved in Phase II, due to lack of critical phenomenological or process data, have, for the most part, been resolved by assumption for purposes of this phase of study. It must be noted, however, that a high degree of judgement has been exercised in making the required selection.

The technical decisions and unknowns associated with this selection are given in Figure I-2.

The unknowns listed in Figure I-2 are those which form the basis for the subsequent definition of experiment and test Work Elements in the R&D portion of the Work Breakdown Structure. It is recognized that current Space Processing programs are addressing such unknowns as macromolecule mobility relationships to resolution, and effectiveness of isoelectric focussing, etc. Resolution of any such unknowns through current or other future programs are not accounted for here, but will, of course, influence the future application of this study's findings.

Baseline process data defining key requirements for the selected process are shown in Section II.2.5.

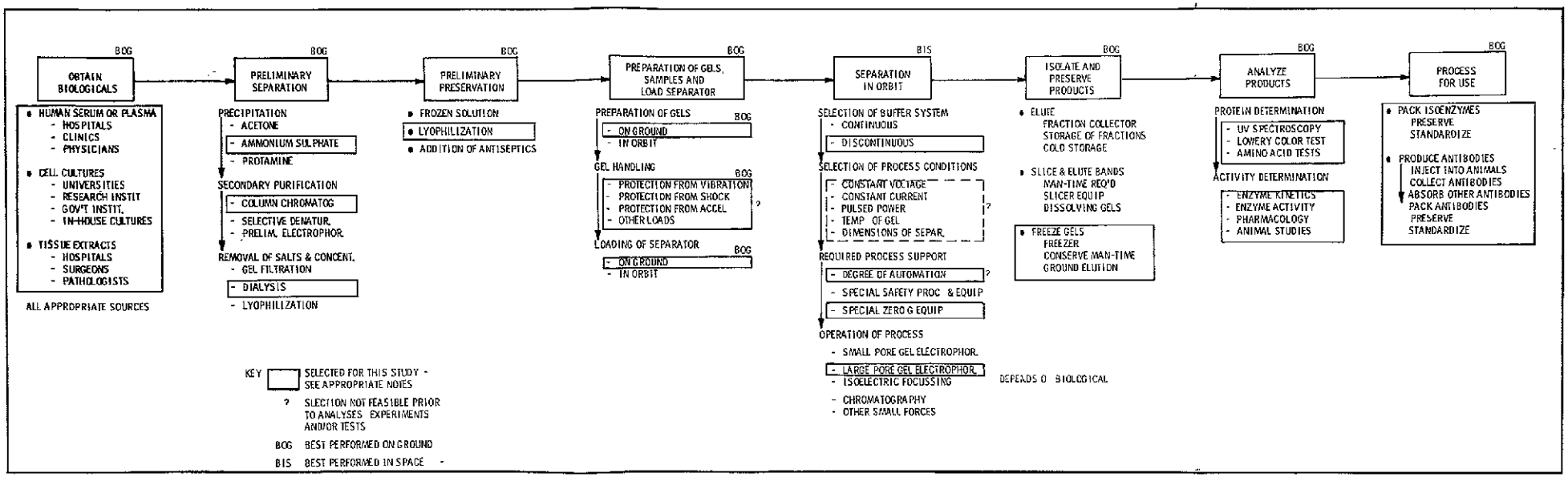


Figure I-1. Definition of Best Implementation Approach for Separation of Isoenzymes

Decisions	Current Preferred Method
1. Choice of gel composition, density, etc.	large pore gel
2. Choice of forming and loading gel prior to launch or in space	prior to launch
3. Selection of Buffer System	Discontinuous
4. Selection of Running Conditions	batch process, small quantities
5. Selection of Separation Method	gel electrophoresis/ isoelectric focussing
6. Selection of Isolation Method	freeze gels
7. Choice of Preliminary Separation method	ammonium sulphate precipitation, columnchromatography, & dialysis
8. Choice of Preliminary Preservation method	lyophilization

Unknowns* Which Require Experiments and Tests for Resolution

1. Dissolving gel possibilities and characteristics.
2. Loss of isolation/resolution in frozen storage.
3. Migration of components under the influence of weak forces.
4. Ability of gel, etc., to withstand launch forces (g's & vibration).
5. Electrophoresis process stability at less than 10 volts/cm.
6. Effects of voltage gradient on enzyme mobility.
7. Relationship of enzyme mobility to resolution.
8. Ohmic heating rates in gels.
9. Convection rates in enzyme bands in gels.
10. Effects of electrophoresis path length on resolution of isoenzymes.
11. Relative effectiveness of large- and small-pore gel electrophoresis and isoelectric focussing.
12. Effects on total process of variations in buffers, gel types, running time, voltage gradient, etc.

Figure I-2. Current Decisions and Unknowns*

SECTION II

DEVELOPMENT PROGRAM

The framework upon which development tasks, schedules, costs, equipment and facility needs, etc. are constructed, is the Work Breakdown Structure (WBS). While relatively unfamiliar outside the Aerospace/Military communities, it is felt to provide sufficiently valuable insight to program planning to warrant its introduction into this commercial product study.

We have, however, deviated from the usual WBS content. The long development effort for products under study, the need for both Space and Ground Processing steps, the obvious comparisons between familiar ground processes and the "new" Space-involving process led us to establish a WBS based on process steps, rather than on equipment. Thus, subsequent analyses could easily compare value added versus cost added for any process step.

This section of the report details the WBS for the Isoenzyme processing program and summarizes the Work Element Descriptions, Work Element Resource Requirements, and Resource costs. Finally, it assembles the Development Schedule.

II.1 WORK BREAKDOWN STRUCTURE

The Work Breakdown Structure against which the development and production tasks are organized is shown in Figure II-1 A&B. Figure II-1A depicts the configuration of the WBS at the top level, while II-1B delineates the detailed structure. The development effort which is documented in over 120 pages of work element descriptions, work element resource needs and resource costs, is summarized in Section II.2.

The technical and business assessment of the in-space isoenzyme separation opportunity requires that all elements of work, from raw materials to finished product be

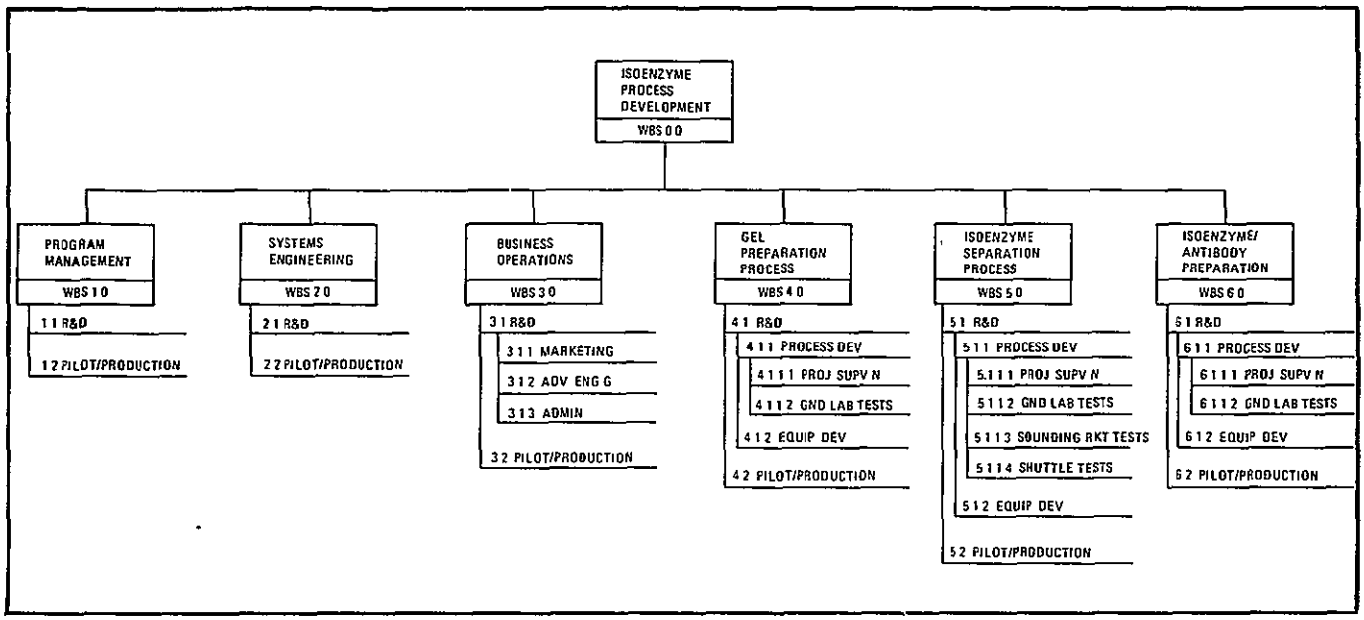


Figure II-1A. Work Breakdown Structure for Isoenzyme Processing

examined, costed and analyzed. The major process steps of the WBS provide a suitable framework for collecting tasks and costs over that sequence of events, and this approach tends to assure that no major business costs are overlooked. Three major process steps are defined for isoenzymes:

Gel Preparation (WBS 4.0)
Isoenzyme Separation (WBS 5.0)
Isoenzyme/Antibody Preparation (WBS 6.0)

In addition, work elements for integrating and planning the development and pilot/production program are added as follows:

Program Management (WBS 1.0)
System Engineering (WBS 2.0)
Business Operations (WBS 3.0)

1.0 Program Management
1.1 Program Management - R&D
1.2 Program Management - Pilot/Production

2.0 System Engineering
2.1 System Engineering - R&D
2.2 System Engineering - Pilot/Production

3.0 Business Operations
3.1 Business Operations - R&D
3.2 Business Operations - Pilot/Production

4.0 Gel Preparation Process Step
4.1 Gel Preparation Process Step - R&D
4.1.1 Process Development
4.1.1.1 Project Supervision
4.1.1.2 Ground Lab Tests
4.1.1.2.1 Launch Environment Testing of Gels (Test IIIB)*
4.1.1.2.2 Storage of Prerun samples w/o Denaturation (Test IIIC)*
4.1.2 Gel Preparation Equipment Development
4.2 Gel Preparation Process Step - Pilot/Production

5.0 Isoenzyme Separation Process (in-space)
5.1 Isoenzyme Separation Process - R&D
5.1.1 Process Development
5.1.1.1 Project Supervision
5.1.1.2 Ground Lab Tests
5.1 1.2.1 Enzyme Mobilities vs Voltage Gradient low V, Test IA*
5.1.1.2.2 Effects of Convective Disturbance on Resolution (Test IB)*
5.1.1.2.3 Use of Long Path Length to Improve Separation (Test IC)*
5.1.1 2.4 Gel Length vs Resolution - Isoelectric Focusing (Test ID)*
5.1.1.2.5 Best Ground Method of Separation (Test IIA)*
5.1.1.2.6 Preparative Scale Separation Tests (Test IIB)*
5.1.1.2.7 Environmental Tests on Standard Equipment (Test IIIA)*
5.1.1.3 Sounding Rocket Tests
5.1.1.3.1 Separator Design & Test (Part of Test IV)*
5 1.1.3.2 Freezer Design & Test (Part of Test IV B)*
5.1 1.3.3 Power Unit Design & Test (part of Test IVC)*
5.1.1.4 Shuttle/Spacelab Tests
5.1.1 4.1 Separator Tests (part of Test IVA)*
5.1.1.4.2 Freezer Tests (part of Test IVB)*
5.1.1.4.3 Power Unit Tests (part of Test IVC)*
5.1.1.4.4 Prototype System Test (Test VA, B, C)*
5.1.2 Equipment Development
5.2 Isoenzyme Separation Process - Pilot/Production

6.0 Isoenzyme/Antibody Preparation
6.1 Isoenzyme/Antibody Preparation - R&D
6 1.1 Process Development
6.1.1.1 Project Supervision
6.1.1.2 Ground Lab Tests
6.1.1.2.1 Post Separation Isoenzyme Storage Effects (Test IIID)*
6.1.1.2.2 Efficacy of Antibodies
6.1.2 Equipment Development
6.2 Isoenzyme/Antibody Preparation - Pilot/Production

*Test Numbers Refer to Tests Identified in Phase II

Figure II-1B. Isoenzyme Work Breakdown Structure Details

Each WBS element above is divided into R&D and Pilot/Production phases, with the R&D phase ending at completion of a prototype capability. Work and cost summaries can thus be obtained either for a process step or for a particular phase. The ability to summarize a process step facilitates comparison of the cost of a process relative to others, assessment of alternatives (e.g. buying of prepared gel tubes rather than in-house preparation), the examination of value added in each process step and examination of the option to sell as a product, the output of a particular process step.

Within each process, work is subdivided as to whether it is Process Development (requirements, system design, subsystem and system tests) or Equipment Development (component design and test based on process development requirements). Hardware breakdown as used in aerospace Work Breakdown Structures occurs as a lower level of Equipment Development.

II.2 WORK ELEMENTS (WORK TO BE DONE)

The development of a ground/space/ground process sequence such as that in Figure II-2 for separation of high specificity isoenzymes can be summarized into the following top level Work Elements:

1.0 Program Management

2.0 System Engineering

3.0 Business Operations

4.0 Gel Preparation Process Step (ground)

5.0 Isoenzyme Separation Process Steps (in-space)

6.0 Isoenzyme/Antibody Preparation Process Step (ground)

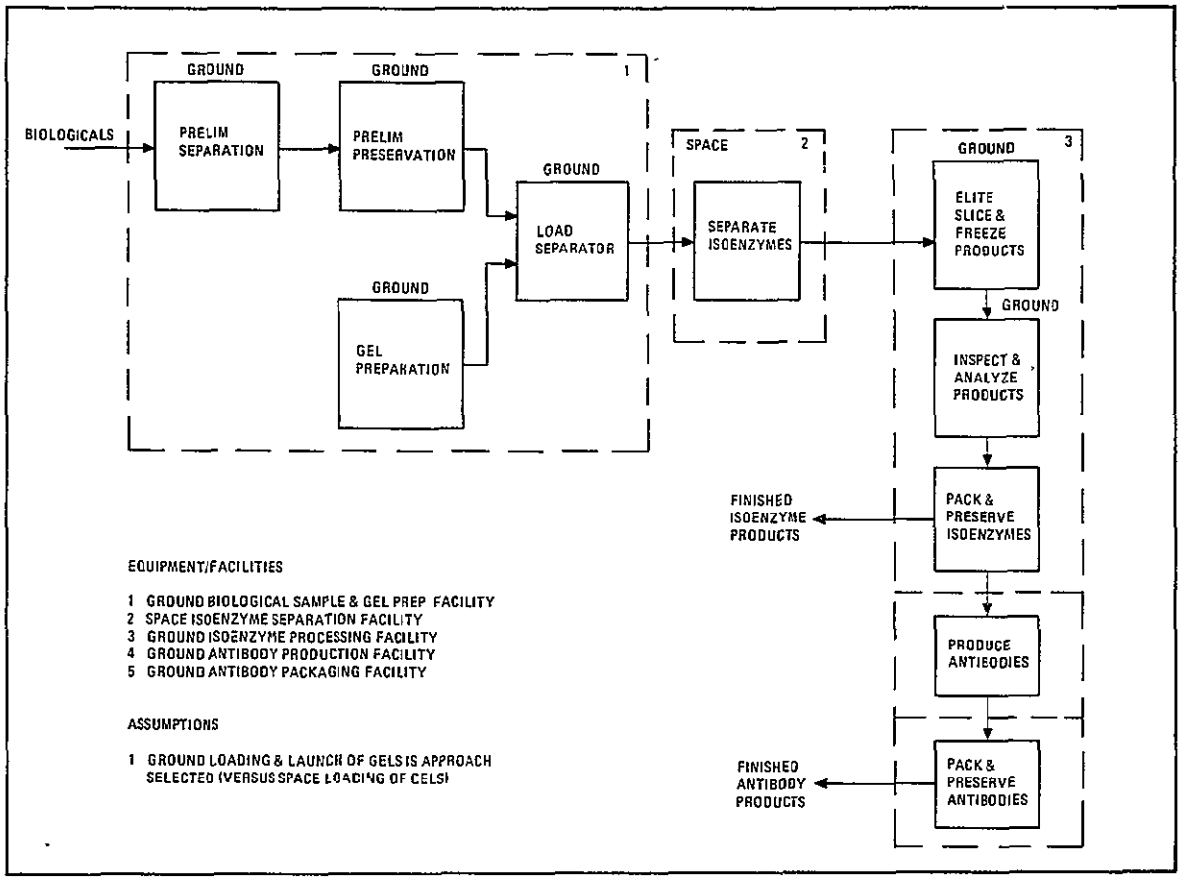


Figure II-2. Isoenzyme Processing Ground/Space Process Steps and Facilities

These elements apply to both the development (R&D) phase and pilot plant and production phases. The R&D effort for Isoenzyme production is largely concentrated in the in-space process step (WBS 5.0) and this development plan accordingly emphasizes that area of work. However, many development activities involve the active participation and close coordination of multiple Work Elements. Typically, the development program includes a series of major experiments and tests shown in Figure II-3A from which the sounding rocket and shuttle tests are further summarized in Figure II-3B. In all cases, there is exhibited a high degree of combined Work Element involvement. A description of the work to be done in each element is given in the following paragraphs.

II.2.1 PROGRAM MANAGEMENT (WBS 1.0)

Program Management in the R&D phase will include the definition of development tasks and schedules, arranging for and controlling the resources needed, and maintaining a management liaison with the parties involved. These parties will include the

				WBS
Separation Evaluation	Process Phenomenology	IA -	Enzyme mobility vs. Voltage Gradient at low gradients Ground Lab - Electrophoresis	5.1.1.2.1
		IB -	Convection current effects on Isoenzyme band resolution Ground Lab - Electrophoresis	5.1.1.2.2
		IC -	Effect of Long Path Length on Isoenzyme Separation Ground Lab - Electrophoresis	5.1.1.2.3
		ID -	Effect of Long Path Length on Isoenzyme Separation Ground Lab - Isoelectric focussing	5.1.1.2.4
		IIA -	Best ground method of Separation Ground Lab - Electrophoresis	5.1.1.2.5
		IIB -	Best scale-up method for Isoenzyme Separation Ground Lab - Preparative-scale separator	5.1.1.2.6
	Environmental Factors	IIIA -	Launch environment effects on standard equipment Ground Environ Test Lab - Electrophoresis	5.1.1.2.7
		IIIB -	Launch environment effects on Gels Ground Environ Test Lab	4.1.1.2.1
		IIIC -	Denaturation effects of Sample storage Ground Lab	4.1.1.2.2
		IIID -	Post-separation Isoenzyme storage effects Ground Lab	6.1.1.2.1
Verification of zero-G Equipment		IVA -	Design test of Separator unit for space operation KC-135, Sounding Rocket, Shuttle	5.1.1.3.1/5.1.1.4.1
		IVB -	Design test of Freezer Unit for space operation KC-135, Shuttle	5.1.1.3.2/5.1.1.4.2
		IVC -	Design test Electrical Power Unit for space operation KC-135, Shuttle	5.1.1.3.3/5.1.1.4.3
Pilot/ Prototype Tests		V A, B, C	Proof test complete Separation System (Prototype) Space Shuttle Laboratory Module.	5.1.1.4.4
		VI	Efficacy of Antibodies Ground Lab	6.1.1.2.2

Figure II-3A. Isoenzyme Test Series

WBS No	Test	Experiment No	Power Req'd (KW)	Experiment Weight (Kg)	Experiment Vol (M^3)	Flight Date (Yr)	Total Experiment Duration	Flight Crew Support Req'd	Flight Vehicle	Data Transmission Requirements	Data Processing Requirements	Energy Requirements (KWH)
51131	Separator Test	IVA	0 3	100	0 3	78	10 min	no	S/R-1	TBD	N/A	0 1
51131	Separator Test	IVA	0 3	100	0 3	79	10 min	no	S/R 2	TBD	N/A	0 1
51132	Freezer Test	IVB	0 3	30	0 2	78	40-100 runs 30 secs each	yes	KC-135	TBD	N/A	0 1
51141	Separator Test	IVA	0 3	200	0 5	80	7 days	14 man hrs	Shuttle SL-1	none	none	30 KWH
51141	Separator Test	IVA	0 3	200	0 5	81	7 days	14 man hrs	Shuttle SL-2	none	none	50 KWH
51142	Prototype/Proof Test	V	0 5	200	0 5	82	7 days	14 man hrs	Shuttle SL 3	none	none	85 KWH
51142	Prototype/Proof Test	V	0 5	200	0 5	83	7 days	14 man hrs	Shuttle SL-4	none	none	85 KWH

Figure II-3B. Sounding Rocket and Shuttle Flight Test Requirements

pharmaceutical research laboratory, product manufacturer, NASA centers, the space system contractor, and NASA contractors. While each development task will include project supervision of that work, Program Management will provide for the overall management of all aspects of the program. The three Work Elements in WBS 1.0 include resource needs for reports, presentations, special documents and plans. Key outside consultation has also been included in Program Management in response to Polysciences' request. When the production phase becomes routine, Program Management is planned to phase out and the planning and control activities are to be handled by administrative and production control functions of the business. Some project engineering services will be required to handle shuttle services and interfaces.

II.2.2 SYSTEM ENGINEERING (WBS 2.0)

In the R&D phase, System Engineering will be required to establish requirements and specifications for design of overall ground-space-ground process sequence and to conduct tests of overall processes. As development tests eliminate the present unknowns and technology gaps, System Engineering will convert these findings to a specific prototype system design (ground-space) and ultimately to a pilot/production mission profile as portrayed in Figure II-4. In commercial terms, this is a combined plant engineering and product engineering activity, with the added dimensions of space vehicle/payload interfacing and orbital operations requirements. The outputs of the R&D System Engineering effort will be overall process and materials specifications and process equipment design requirements. In the routine production phase, System Engineering phase out and is replaced by Advanced Engineering. The three Work Element descriptions under System Engineering provide for such resource needs as computer services and equipment test facilities.

II.2.3 BUSINESS OPERATIONS (WBS 3.0)

Business Operations in the R&D phase will be concerned with business preparations is anticipation of a successful development effort and initiation of production. Business planning must be done continuously as a basis for investment decisions as R&D results are obtained. Three areas of business operations are described as follows:

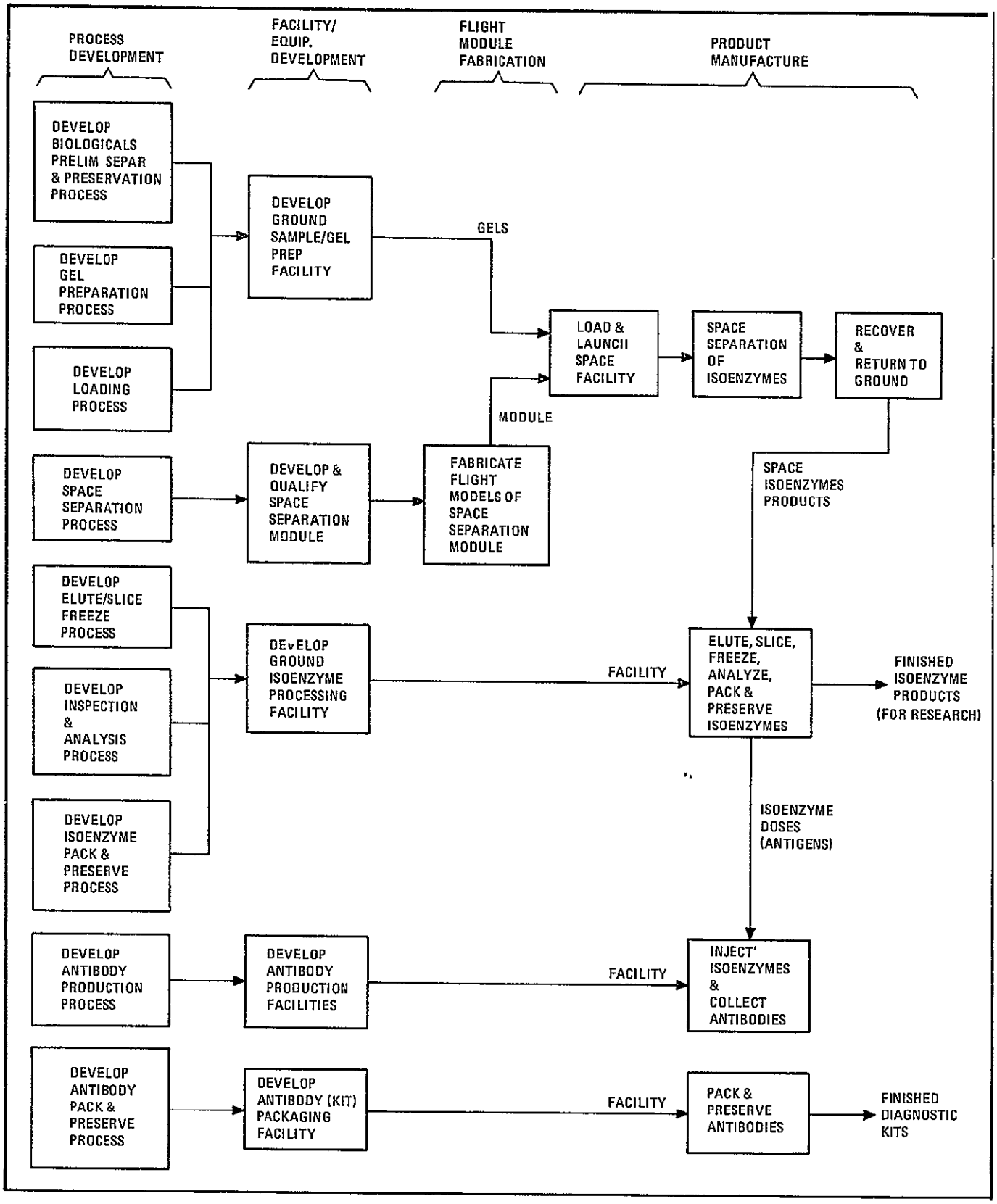


Figure II-4. Isoenzymes Production - Development and Mission Profile

WBS 3.1.1 MARKETING

Development program initiation is necessarily based on very early estimates of business viability and financial returns. During the R&D activity, Marketing must continuously analyze the potential market, market share, anticipated orders, product offerings, gross margins, product costs, profits, etc. in order to confirm or modify earlier plans. As the time of pilot production approaches, Marketing will prepare sales literature, preliminary catalog data, and price data as the basis for customer contact. The product distribution system will be designed and an appropriate sales organization will be initiated. Demonstrations of product characteristics and performance will be conducted using samples from early tests and prototype/pilot runs to convince customers of product advantages and to establish a preliminary seller/purchaser understanding. Advance orders will be solicited, as early as possible in the R&D phase to reduce the risk associated with a commitment to build production facilities. When the production phase begins, Marketing will conduct routine order processing, cataloging, product service, product planning, and sales engineering activities as well as future market/business planning.

WBS 3.1.2 ADVANCED ENGINEERING

Advanced Engineering will be relatively quiescent during the R&D phase since the R&D System Engineering and R&D Experiment and Test tasks will be accomplishing that function. A limited amount of second generation technical investigation will be done to explore opportunities which lie beyond the scope of the R&D effort. These findings may have an effect on the direction of the R&D effort. When the production phase begins, Advanced Engineering work will increase to develop improvements on the pilot/production design and to introduce new processes and facilities as suggested by Marketing plans.

WBS 3.1.3 FINANCIAL, LEGAL & RELATIONS SUPPORT

In the R&D phase, the Finance, Legal, & Relations functions will participate with Marketing in the preparation and critique of business plans, and recommending of

steps to be taken by management to prepare for production. The timing and amount of investments will be critical, with pressures to move quickly to establish a market position, and concurrent pressures to postpone action, to reduce financial risk. Relations will be concerned with staffing of R&D positions and planning for production staff. Legal will address the contract/subcontract terms anticipated for production and the insurance/indemnity/warranty provisions that are planned to be used. This work will include establishing of the terms for using NASA Shuttle and other space facility services, as well as defining the associated manufacturer/NASA liabilities.

II.2.4 GEL PREPARATION PROCESS STEP (WBS 4.0)

The R&D effort on this step of Isoenzyme production is comprised of 8 Work Elements which will examine the basic phenomenology of gel types, gel constraint methods, ground environmental influences and storage effects, to arrive at a gel tube which is appropriate for space processing. The effort will attempt to define the specific gel type (composition, density) among a number of alternatives, the gel tube characteristics, including tube plugging or other closure methods, and the proper handling and preparation methods to be used. A series of ground tests such as indicated in Figure II-5A will be conducted for this purpose. In addition, the selected gel products will be used in WBS 5.0 Work Elements for subsequent in-space testing. The question of gel life in storage will be answered by a series of storage tests followed by examination of gel condition. The gel preparation process will be affected by the results of in-space tests, in that the success or lack of success in use of gel tubes of various lengths, diameters, capping methods, etc. will confirm or require modification of the gel preparation techniques. The effects of launch forces on gel tube packaging must also be examined as noted in Figure II-5B. The test series will attempt to fill the knowledge gaps and establish a prototype gel preparation process, starting with experimental quantities and expanding to preparative-scale quantities.

In the pilot/production phase, scale-up of prototype designs is expected to be feasible without encountering major development questions. That is, scale-up should be possible by merely increasing the throughput of an already established tube configuration and gel type.

A EXPERIMENTS TO VERIFY SELECTED APPROACH FOR SEPARATION OF ISOENZYMES

FACILITY	EXPERIMENTS AND VERIFICATION TESTS	OBJECTIVES	EXPERIMENT AND TEST REQUIREMENTS (SUMMARY)
GROUND LAB	Tests of specific enzymes in various gels at specific voltage gradients, and on a closely spaced set of isoenzymes at established mobility	Relationship of enzyme mobility in gels to voltage gradient (gradients < 10 V CM) and relationship of mobility to isoenzyme resolution	Standard ground lab, standard electrophoretic separator (typically, Hoeffer DE102) and peripherals, controlled voltage gradients (< 10V/CM) isoenzyme sets (Esterases, Alkaline Phosphatases, Hexosaminidases) photographic and measurement equipment, analytical staining apparatus, 10-15 hours per run Manual loading, initiation, adjustments, termination, sample transfer, automated running.
	Tests using small temperature sensors in gel during electrophoresis at various voltage gradients to determine heating and convective effects on separated bands	Measurement of local heating within a gel during electrophoresis and rate of convective disturbance of enzyme bands in gels	Standard ground lab, equipment as above plus controllable (10 20°) heaters tailored to electrophoresis tubes, thermocouples in gel, 2 days per run
	Tests on a closely spaced set of isoenzymes at various path lengths	Relationship of path length to resolution of isoenzymes	Standard lab, modified standard electrophoretic separator to accommodate longer (probably helical) tubes, selected voltage gradients, selected isoenzyme system, analytical staining apparatus, and automated tasks as above
	Tests of several specific isoenzyme systems to compare large and small pore gel and isoelectric focussing systems, varying buffer, gel types, running time, voltage gradient, etc	Best separation method	Standard ground lab, standard electrophoretic separator (initially, modified or new later), equipment to carry out large and small pore electrophoresis (several gels) isoelectric focussing, various buffers, voltage regulation, photographic and measurement equipment, analytical staining apparatus, 1 day per run Manual and automated tasks as above
	Tests of preservative additives form of preservation and environments	Best method of preservation of specimens -- prelaunch	Environmental chamber (temperature humidity pressure) controllable for various pre flight conditions. Lyophilized buffered refrigerated specimens Biological assay equipment Up to 8 weeks per run Automated with manual assay
	Techniques to store and reconstitute for separation	Best method of preservation of specimens orbital preparation for separation	Standard ground lab samples from lyophilized buffered refrigerated specimens reconstitution equipment (hydration heating) Biological assay equipment Up to 1 day per test Manual
	Handling techniques preservatives form of preservation and environments to preserve separated isoenzymes	Best method of preservation of separated isoenzymes to maintain biological life and purity and physical separation and for post flight biological adequacy	Standard ground lab for Lyophilization buffering, refrigerating of separated isoenzymes as above

Figure II-5A. Typical Gel Preparation Ground Tests

FACILITY	EXPERIMENTS AND VERIFICATION TESTS	OBJECTIVES	EXPERIMENT AND TEST REQUIREMENTS (SUMMARY)
CENTRIFUGE	Environmental tests (e g , shock, temperature, vibration, acceleration, etc.).	Effects of launch environments on equipment, specimens, gels, buffers, etc	Programmable centrifuge, gondola-mounted vibration, shock, heating equipment, various gels, other separation-related components, specimens, temperature, vibration, load-measuring instrumentation 30 minutes per run Automated.
	Test preserved products for recovery environs	Best method of preservation of separated isoenzymes to maintain biological life and purity, and physical separation and for post flight biological adequacy	Programmable centrifuge with vibrator to simulate recovery loading. ~ 1 hour per run Automated bio-assay equipment for determination of bio quality ~ 8 weeks per run Manual
ENGINEERING LAB	Tests of preparative scale equipment to assess scale up effects on ohmic heating convection resolution	Scale-up parameters and design limits	Standard ground lab new large scale separator selected buffer voltage gradient peripheral equipment for selected separation method test instrumentation, analytical staining apparatus photographic and measurement equipment 1 day per run Manual and automated tasks
	Techniques to store and reconstitute for separation	Best method of preservation of specimens orbital preparation for separation	Standard ground lab samples from lyophilized buffered, refrigerated specimens reconstitution equipment (hydration, heating) Biological assay equipment Up to 1 day per test. Manual
KC-135	Zero-G aircraft tests of process equipment	Effects of space environments on the selected separation process, equipment design	Short term Zero G ' tests of buffer storage and transfer specimen injection cooling system, etc. designs (materials bubble control, etc)

Figure II-5B. Typical Gel Preparation Ground Tests (Cont'd)

II.2.5 ISOENZYME SEPARATION PROCESS STEP (WBS 5.0)

A major R&D effort of 22 Work Elements is required to examine the phenomenology of this key step in isoenzyme production. Typical requirements for this process step are shown in Figure II-6 for both the baseline production process and a typical experiment.

After successful operation of the process on an experimental basis, further R&D will be required to establish the preparative scale equipment and processes as necessary for economical throughput. Fundamental questions on appropriate voltage gradients, convection rates, local heating, gel tube effects, path length, buffer type, etc., must be answered at both the experimental and preparative scale levels. Throughput requirements (on the order of thousands of milligrams of separated antigens per year) raise further questions of tube size, tube insertion and removal, chamber emptying in zero-G, etc., which can only be resolved with shuttle tests of preparative scale equipment. A series of tests is necessary to examine basic phenomena in the ground laboratory environment followed by sounding rocket and shuttle flight tests to achieve a prototype capability.

Figure II-7, II-8, II-9 are representative Work Element Descriptions, resource requirements and resource costs generated for tests covered in this WBS. Initial tests will use conventional single or multiple gel tubes of nominally 0.5 cm diameter, as shown typically in Figure II-10. Scaleup efforts will attempt the use of tubes of 5-8 cm diameter, as conceived in Figure II-11, to increase the antigen output per run while minimizing handling requirements and chamber complexity.

We have also looked at a less conventional separation system, Figure II-12, which, while it may require more development, appears to be better suited to high output requirements of preparative quantities.

Item	Typical Experiment Data	Production Data
Gel Temperature	5°C	5°C
Gel Type	large pore gel	large pore gel
Buffer Type	discontinuous	discontinuous
Batch Size	few mg	100 mg
Tube Length	7.5 cm	20-25 cm
Tube Diameter	0.5 cm	5-8 cm
No of Tubes	1 to 9	1
Voltage Gradient	<10 volts/cm	<10 volts/cm
Voltage Applied	100-400 volts	300-1300 volts
Current	2 ma	200-400 ma
Power Required (process)	1 watt	100-500 watts
Separation Process	gel electrophoresis (or isoelectric focusing)	gel electrophoresis (or isoelectric focusing)
Biological Materials	creatine kinase, etc.	creatine kinase, etc.
Storage Method	freezer	freezer
Isolation Method	Elution (on ground)	Elution (on ground)
Preliminary Separation Method	Ammonium sulfate precipitation, column chromatography, & dialysis	Ammonium sulfate precipitation, column chromatography, & dialysis
Preliminary Preservation Method	lyophilization	lyophilization
Process Time		
Buffer Prep Time		1 hr } on ground
Gel Prep Time		1.5 hr — —
Separator Prep Time (Tubes, Buffer, Cooling)		0.5 hrs } in-space
Electrophoretic Run Time		10-15 hrs }
Gel Removal Time		0.3 hrs
Gel Placement in Staining Solution Time		0.1 hr
Gel Stain Time		4-5 hrs } on ground
Stain Wash Time		10 hrs
Gel Placement in Preservative Time		0.1 hr
Gel Measure & Photograph Time		1 hr

Figure II-6. Isoenzyme Separation Process Baseline Requirements

TASK DESCRIPTION

TASK TITLE: Demonstration of Capability to Perform Pre. Scale Separation

WBS NO.	PREPARED BY	DATE
5.1.1.2.6	S.L.	7/11/74

1. REQUIRED OUTPUT:

Report on quality of resolution in scale up of five promising isoenzyme systems to preparative scale electrophoresis. Isolation of separated products for further study.

2. REQUIRED INPUT:

Based on 5.1.1.2.5, selection of five isoenzyme systems according to their diagnostic reliability and separation potential.

3 DESCRIPTION OF EFFORT:

1. Tissue/sera collection - as in 5.1.1.2.5, but larger amount required.
2. Tissue prep - as in 5.1.1.2.5.
3. Purification - as in 5.1.1.2.5.
4. Electrophoresis - set up of prep unit, electrophoresis as in 5.1.1.2.1.
5. Report - writing and preparation.

4 PERFORMANCE PERIOD: For each of the five isoenzyme systems, 1 week of prep runs. Timetable - after 5.1.1.2.5, third quarter of 1976.

PERFORMANCE RESPONSIBILITY:	APPROVAL
Ground Lab	

NOTE CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED

BUS-1

Figure II-7A. Typical Work Element Task Description for Ground Test of Separation Process

TASK RESOURCE REQUIREMENTS

TASK TITLE		
Demonstration of Capability to Perform Preparative Scale Separations		
WBS NO. 5.1.1.2.6	PREPARED BY S.L.	DATE 7/11/74

1. PURCHASED MATERIALS: (INCLUDE ASSUMPTIONS)

Chemical reagents*, stains*, colorigenic enzyme substrates**, photographic supplies*, misc, lab glassware*

*Same as needed for 5.1.1.2.1
**Same as needed for 5.1.1.2.5

2. PURCHASED SERVICES: (INCLUDE ASSUMPTIONS)

Pathologist*, clinician*, building of preparative separator (if commercially available units are not acceptable)

*Same as needed for 5.1.1.2.5 but for 1/2 time.

3. EQUIPMENT: (INCLUDE ASSUMPTIONS)

Prep. electrophoresis separator, power supply*, copying camera*, storage refrigerator*, cooling bath (circulating), glass chromatography columns*, centrifuge (clinical)*, deep freeze*, homogenizer*, microscope*, UV spectrophotometer*, fraction collector*, freeze drying unit*, vacuum pump*.

*Same as needed for 5.1.1.2.5.

4 FACILITIES (INCLUDE ASSUMPTIONS)

One lab *12' x 12' equipped with electrical, plumbing, furniture and hood.

*Same as needed for 5.1.1.2.5.

	APPROVAL

NOTE CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED.

BUS-3

Figure II-7B. Typical Work Element Task Resource Requirements for Ground Test of Separation Process

WORK ELEMENT COSTS							
WORK ELEMENT NO. 5 1.1.2.6	WORK ELEMENT TITLE Capability to Perform Preparative Scale Separation						
1 ACT. NO.	2 ACTIVITY	3 LABOR COST	4 PURCHASED MATERIALS COST	5 SERVICES COST	6 EQUIPMENT COST	7 FACILITIES COST	8 TOTAL COST
1	Tissue/sera collection	640	***	150 125	-	-	915
	Planning	800 525					
	Prep/Run	800 1050	250	1100	1100	-	7,750
	Post Run/Assay	1600 525					
2	Report	640 380	11	-	-	-	1,031
3	Tissue Prep	95 525	55	-	**	-	675
4	Purification	320 2100	250	-	**	-	780
**Equipment Used in 5.1 1.2.5 ***Assuming no cost							
	TOTALS	$10,000	$566	$1375	$1100	-	$13,041

Figure II-7C. Typical Work Element Task Cost for Ground Test of Separation Process

TASK DESCRIPTION

TASK TITLE: KC-135 (Zero G) Tests of Freezer Unit

WBS NO	PREPARED BY	DATE
5.1.1.3.2	PTS	12.74

1 REQUIRED OUTPUT:

Design confirmation and report on operation of freezer and cooling system on short duration zero-g conditions.

2. REQUIRED INPUT:

Results of WBS 5.1.1.2.8.

3. DESCRIPTION OF EFFORT:

(See Test IVB)

1. Assemble and ground test a freezer unit and cooling system as developed in WBS 5.1.1.2.3, and package for KC-135 flights.
2. Conduct KC-135 flight tests (40 to 100 runs, 30 seconds per run) to assess freezer operation and cooling system operation at zero-g for short durations in various positions.
3. Conduct post-flight ground tests and design analysis of returned equipment to assess equipment design.

4 PERFORMANCE PERIOD

After 5.1.1.2.8, 1975/79.

PERFORMANCE RESPONSIBILITY:	APPROVAL
Research Lab/Systems Contractor/NASA	

NOTE CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED

Figure II-8A. Typical Work Element Task Description for KC-135 Test of Freezer Unit

BUS-1

TASK RESOURCE REQUIREMENTS		
TASK TITLE: KC-135 (Zero-g) Tests of Freezer Unit		
WBS NO. 5.1.1.3.2	PREPARED BY PTS	DATE 12/74

1. PURCHASED MATERIALS (INCLUDE ASSUMPTIONS)

Film and other photographic supplies; raw materials for experiment package structure and mounting interconnection, etc.

(Assume freezer and recorder available from other tasks)

2. PURCHASED SERVICES (INCLUDE ASSUMPTIONS)

Project engineering, apparatus design and fabrication, flight preparation, flight support and post-flight data analysis.

(Assume KC-135 aircraft and NASA support are GFE)

3. EQUIPMENT; (INCLUDE ASSUMPTIONS)

None (assume freezer and recorder are available from other tasks)

See Figure II-8D

4 FACILITIES (INCLUDE ASSUMPTIONS)

None

	APPROVAL

NOTE: CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED

BUS-3

Figure II-8B. Typical Work Element Task Resource Requirements for KC-135 Test of Freezer Unit

WORK ELEMENT COSTS							
WORK ELEMENT NO. 5.1.1.3.2	WORK ELEMENT TITLE KC-135 (Zero-G) Tests of Freezer Unit						
1 ACT. NO.	2 ACTIVITY	3 LABOR COST	4 PURCHASED MATERIALS COST	5 SERVICES COST	6 EQUIPMENT COST	7 FACILITIES COST	8 TOTAL COST
1	Preflight ground test	1280	3500	5000	-	-	9780
2	Flight Test - Contractor	-	-	2500	-	-	2500
	NASA Support	-	-	15,000*	-		14,000*
3	Postflight Ground Test & Analysis	1280	-	4000	-	-	5280
*KC-135 Aircraft and NASA support							
	TOTALS	$2560	$3500	$26,500	-	-	$32,560

Figure II-8C. Typical Work Element Task Cost for KC-135 Test of Freezer Unit

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 1

EQUIPMENT NAME	DATE
Freezer (Storage & Preservation) (B 24 E)	12/31/75

1. AVAILABILITY STATUS

- [X] **NEW, REQUIRES** **YEARS TO DEVELOP** So-Low Environmental Equipment Co.,Inc.
- [ ] **MODIFICATION OF AVAILABLE EQUIP; COMPANY**
- [ ] **PRESENTLY AVAILABLE; COMPANY**
- [ ] **SPACE QUALIFIED, PROGRAM**
- [ ] **OTHER**

2 EXPERIMENTS ACCOMMODATED (EXPERIMENT NAME OR TYPE)

- Biological Applications

3 DESCRIPTION OF EQUIPMENT OPERATION (MAJOR FUNCTIONS)

- The unit will be utilized for cold storage or biological samples, before and after processing.

Functions: a) Separate sections within the storage compartment with programmable temperature control
b) Hold containers within each section to provide positive containment and to prevent shock damage during launch/landing.
c) Have sufficient insulation, thermal inertia, secondary cooling capacity in case of primary power malfunction.

4. EQUIPMENT PHYSICAL DESCRIPTION (SKETCH, DIMENSIONS, VOLUME)

- No. Req'd - 1
- .54m x .84m x .30m = .136m^3
- wt - 80 kg.

5 EQUIPMENT PERFORMANCE PARAMETERS (E.G , FLOW RATE, ENERGY OUTPUT, MAX TEMP , ETC)

- Temp. Range - -18°C to -184°C (Accuracy ± 1°C)
- Thermal Capacity - 375 btu/hr at -160°c

Figure II-8D. Freezer Data (Page 1 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 2

EQUIPMENT NAME	DATE
Freezer (Storage & Preservation) (B 24 E)	12/31/74

6. INSTRUMENTATION: (E.G., THERMOCOUPLES, GAUGES, ETC, LOCAL & REMOTE)

- Temperature Sensing Device

  a) Maximum temperature fluid expansion thermometers.
  b) Chemically treated maximum temperature indicating paper discs.

7. SUPPORT SERVICES REQUIRED (E.G , POWER, GASSES, VACUUM, COOLANT, OPERATOR ATTENTION)

- Power is from 115V-60Hz main power supply

  500w peak
  100w sustained

8. EXTERNAL ENVIRONMENT REQUIRED (E.G , ATMOSPHERE, VIBRATION LEVEL, ETC)

- Forced cooling of motors and compressors will be necessary.

9 EXTERNAL ENVIRONMENT PRODUCED: (E.G., EMI, HEAT, CONTAMINATION, ETC)

- EMI generation during compressor start up.

10 SAFETY CONSIDERATIONS (EQUIPMENT, OPERATORS, ETC)

- Guarded against spillage of the fluids.
- Glass covers are replaced by polycarbonate plastic.
- Refrigerant may be inflammable at the surrounding environment.

11. WASTES & PRODUCTS PRODUCED

- None

Figure II-8D. Freezer Data (Page 2 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 3

EQUIPMENT NAME	DATE
Freezer (Storage & Preservation) (B 24 E)	12/31/75

12. DATA INPUT/OUTPUT REQUIREMENTS (AS EXTRACTED FROM ITEM 13)

Input Control Functions - Programmable temperature selection & regulation.

Output Temperature Monitoring

13 FUNCTIONAL FLOW DIAGRAM (INCLUDE & NOTE AUTOMATED FUNCTIONS, DATA FLOW, CONTROL RANGES & LIMITS, ETC)

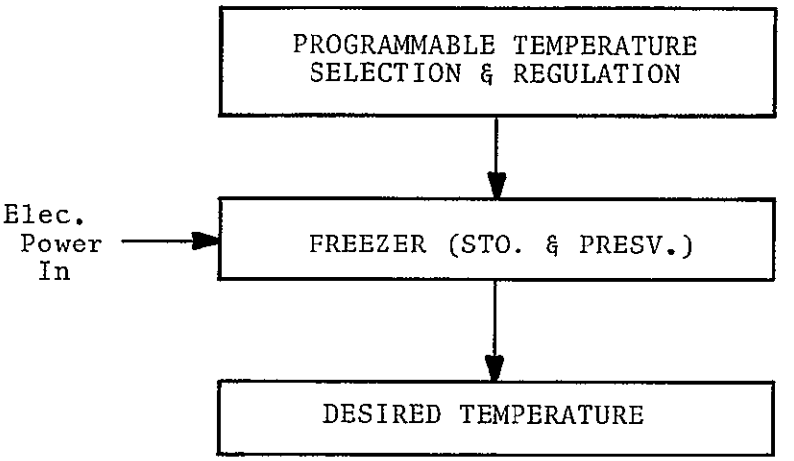


Figure II-8D. Freezer Data (Page 3 of 3)

TASK DESCRIPTION

TASK TITLE
Shuttle Tests (Zero-G) of Separation System

WBS NO.	PREPARED BY	DATE
5.1.1.4.1	PTS	12/74

1 REQUIRED OUTPUT:

Design configuration and report on operation of electrophoresis system (separator, freezer, cooling system, power unit) in zero-G for long durations. Recommendations for design modification to improve operation in zero-G.

2 REQUIRED INPUT:

Results of WBS 5.1.1.3.1, 5.1.1.3.2, 5.1.1.3.3.

3. DESCRIPTION OF EFFORT:

(See Test IV A)

1. Assemble and ground test an electrophoresis separator system (separator, buffer storage and transfer, specimen loading, cooling system, automation & controls) as developed in WBS 5.1.1.3.1, 5.1.1.3.2 and 5.1.1.3.3, and package for shuttle experimental flights.

2. Conduct shuttle test flights (1 to 2 flights, 1 or 2 runs of 1 day each) to assess system operation in long duration zero-g conditions. Gather photographic and other data.

3. Conduct ground lab tests of returned equipment and get to assess equipment design and electrophoretic separation results.

4 PERFORMANCE PERIOD

After 5.1.1.3, 1979-1982

PERFORMANCE RESPONSIBILITY:	APPROVAL
Research Lab/Systems Contractor/NASA	

NOTE CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED

BUS-1

Figure II-9A. Typical Work Element Task Description for Shuttle Test of Separator System

TASK RESOURCE REQUIREMENTS

TASK TITLE		
Shuttle Tests (Zero-G) of Separator System		
WBS NO. 5.1.1.4.1	PREPARED BY PTS	DATE 12/74

1. PURCHASED MATERIALS (INCLUDE ASSUMPTIONS)

Raw materials for construction and modification of apparatus; photographic and biochemical supplies.

2. PURCHASED SERVICES (INCLUDE ASSUMPTIONS)

Systems contractor apparatus fabrication and test, flight support, and post flight data analysis (Assume Shuttle service and NASA support as GFE)

3 EQUIPMENT: (INCLUDE ASSUMPTIONS)

Monitoring equipment and experiment apparatus (pump, valves, controls)

4. FACILITIES (INCLUDE ASSUMPTIONS)

None

	APPROVAL

NOTE: CONTINUE NUMBERED ITEMS ON SEPARATE SHEET AS REQUIRED.

BUS-3

Figure II-9B. Typical Work Element Resource Requirements for Shuttle Test of Separator System

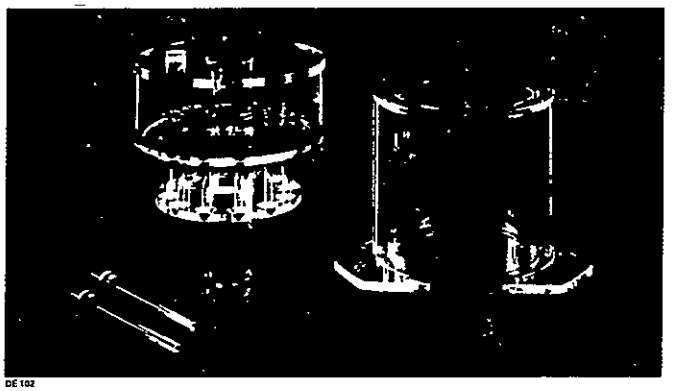
WORK ELEMENT COSTS							
WORK ELEMENT NO. 5.1.1.4.1	WORK ELEMENT TITLE Shuttle Tests (Zero-G) of Separator System						
1 ACT. NO.	2 ACTIVITY	3 LABOR COST	4 PURCHASED MATERIALS COST	5 SERVICES COST	6 EQUIPMENT COST	7 FACILITIES COST	8 TOTAL COST
1	Equipment preparation and test (2 flights)	26000	80000	95000	72000	--	201,000
2	Flight Test (2 flights)	-	-	18000	-	--*	18,000
	NASA Space Charges	-	-	264000	-	--	264,000
3	Post-flight test (2 flights)	2400	2000	8000	-	--	34,000
	TOTALS	$50,000	$10,000	$385,000	$72,000	--	$517,000

Figure II-9C. Typical Work Element Task Costs for Shuttle Test of Separator System

POLYSCIENCES, INC.

PAUL VALLEY INDUSTRIAL PARK WARRINGTON PENNA 18976 PHONE 215--343-6484

EQUIPMENT AND CHEMICALS FOR POLYACRLYAMIDE GEL ELECTROPHORESIS



DE 102

HOEFER electrophoresis unit—polyacrylamide gel

Versatile

Up to 12 gel tubes fit in the upper buffer chamber

The standard lower buffer chamber accommodates gel tubes from 2½' to 5 ' long an optional lower chamber allows tubes up to 8" long

The standard single walled chamber is well suited for work at ambient temperatures for temperature control work a double walled thermojacketed chamber is available

Separation and destaining can be accomplished in the same unit

Convenient

The whole unit is compact enough to fit easily into a refrigerator

Rubber stoppers are fitted on the gel tubes *before* the glass tubes are placed in the tapered holes of the upper chamber eliminating cumbersome manipulation inside the unit

An affixed level and levelling screws insure perfect vertical alignment A tube aligning plate simplifies the alignment pro cedure and is easily visible because transparent plastic is used throughout the unit

Safe

Great strength is achieved by using ¼ thick acrylic plastic in both the upper and lower buffer chambers

The sealed central power core is the only source of current giving positive protection against accidental contact with buffer

Electrodes running in protected grooves around the outside surface of the power core are at all times out of reach of the operator s hands

A safety lid makes certain that the unit cannot be opened while the special plug and voltage cables are attached

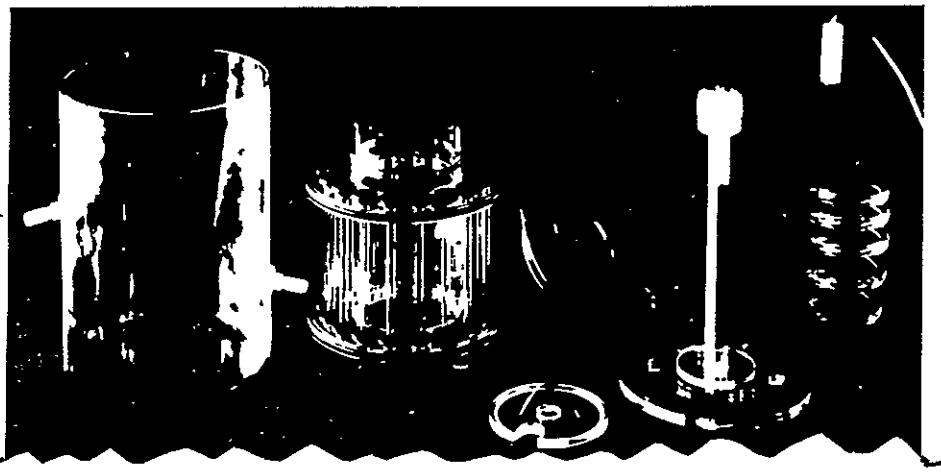


Figure II-10. Typical Available GEL Electrophoresis Units

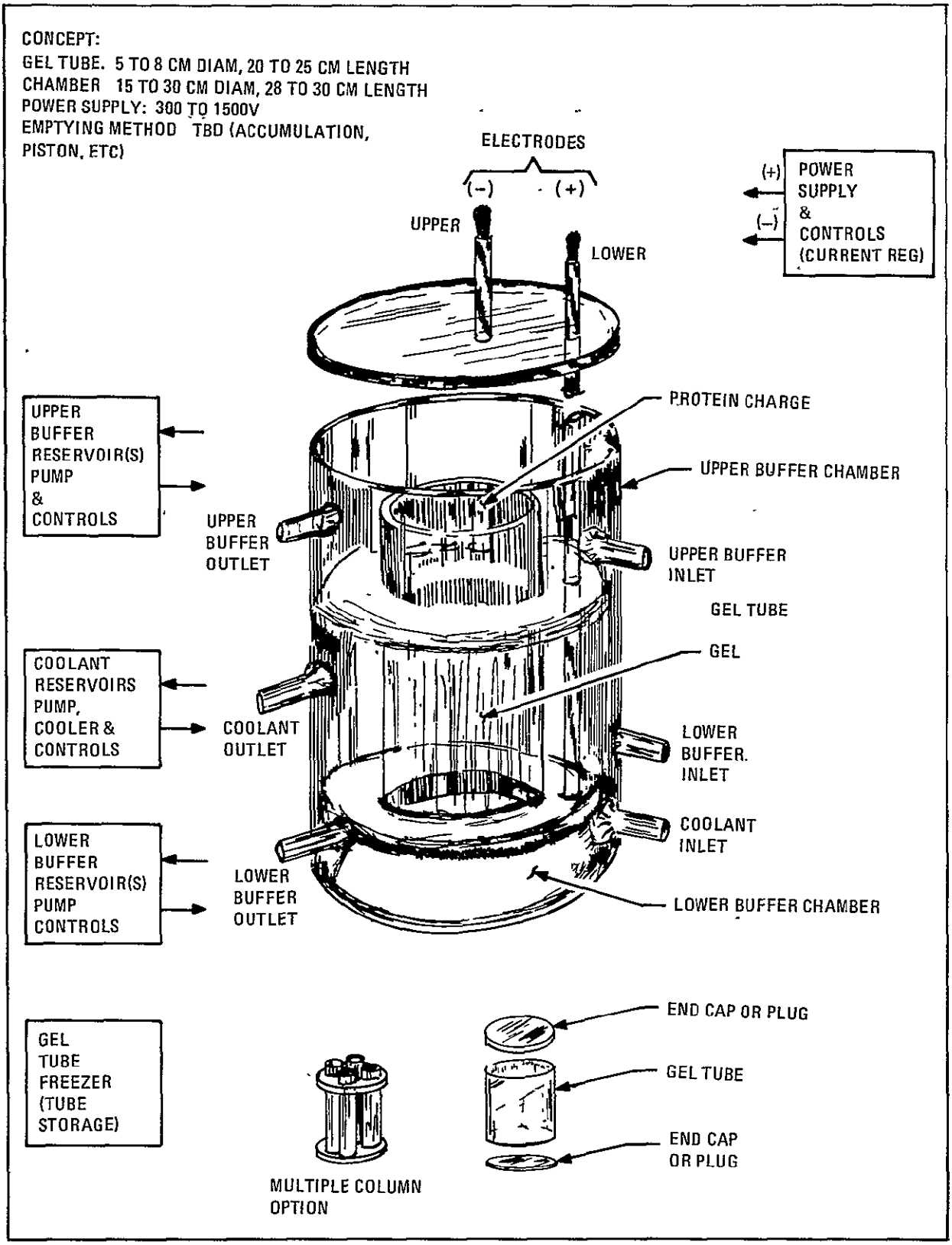
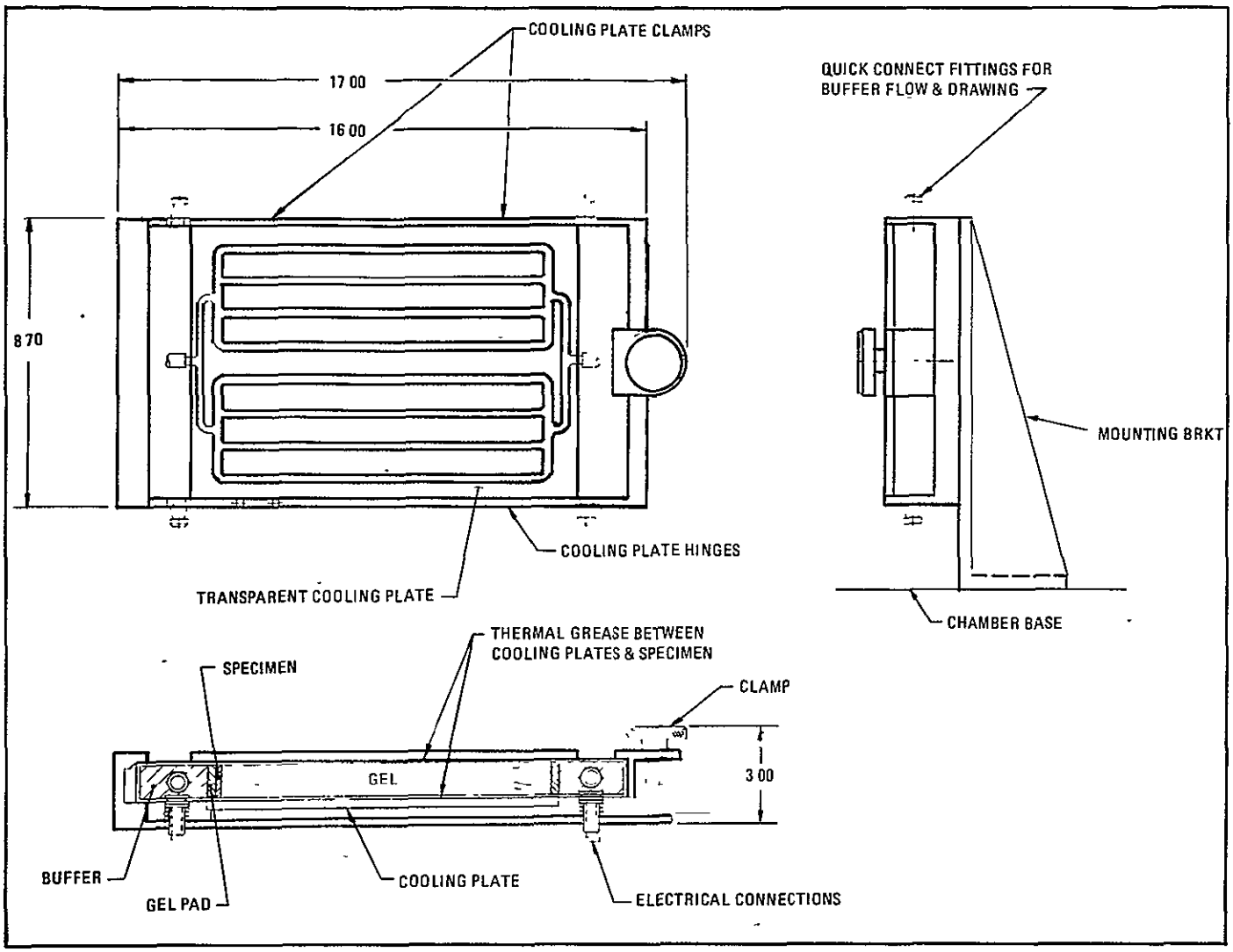


Figure II-11. Large Pore Gel Electrophoresis Facility Concept



ITEM	WEIGHT (KG)	VOLUME (M^3)
SEPARATOR (SINGLE TUBE)	3.6	01
BUFFER	5.5	–
POWER SUPPLY	9.2	.03
FREEZER	81 8	.14
COOLING SYSTEM	13.6	.06
COOLANT	13.6	–
CONTROLS	4 5	.02
STRUCTURE & MISC	48.2	24
TOTAL	180 KG	50 M^3

Figure II-12. Large Pore Gel Electrophoresis Facility Concept-Rectangular Duct Approach

A third approach has been documented by TRW[2], as a Beckman version. Its capabilities are given in Figure II-13.

Other equipment potentially capable of being utilized in this process step are documented in Figures II-14, II-15, and II-16.

While further scaleup of small tube systems can be accomplished by increasing the number of separation chambers on a flight, once an acceptable configuration has been demonstrated, our conclusion is that the rectangular duct separator will likely be the best business solution. It is shown in Figure II-17, as it would be mounted for testing in a rack of the Spacelab. For commercial operations, we feel that the items listed in Figure II-18 represent the state of equipment, and the quantities needed for this program.

Past space processing study experience[3] has indicated the need for early identification and definition of special requirements related to space processes. Figure II-19 lists special requirements reviewed for Space Processing of Isoenzymes.

II.2.6 ISOENZYME/ANTIBODY PREPARATION PROCESS STEP (WBS 6.0)

An R&D effort for this process step is required in order to establish the experimental and preparative techniques for physical removal of antigens from gel tubes as received from the in-space process step (WBS 5.0). Techniques must also be developed for subsequent processing to achieve a final product (gamma globulin fraction) and production of commercial quantities. This process step will require:

- gel removal from tube, slicing and antigen slice selection
- antigen grind, buffer, and freeze dry
- preparation of animal injections

---

[2] Requirements and Concepts for Materials Science and Manufacturing in Space Payload Equipment Study, NAS 8-28938, July, 1973.

[3] Wouch, G and Bloom, H, Free Suspension Process-A Review of Selected User Interests and Requirements, AIAA Paper No. 74-649, AIAA/ASME 1974 Thermophysics and Heat Transfer Conference, July 15-17, 1974.

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 1

EQUIPMENT NAME	DATE
Stationary Electrophoritic Column (B 12 E)	1/2/75

1. AVAILABILITY STATUS

- [X] NEW, REQUIRES YEARS TO DEVELOP (Beckman Instruments)
- [ ] MODIFICATION OF AVAILABLE EQUIP; COMPANY
- [ ] PRESENTLY AVAILABLE; COMPANY
- [ ] SPACE QUALIFIED; PROGRAM
- [ ] OTHER

2. EXPERIMENTS ACCOMMODATED. (EXPERIMENT NAME OR TYPE)

- Biological Applications

3. DESCRIPTION OF EQUIPMENT OPERATION (MAJOR FUNCTIONS)

- The buffer solution is placed in the column.
- The operating voltage gradient and processing temp. are established.
- The sample to be separated is injected into the column.
- The separation process is monitored.
- The desired fractions are collected at the end of the process.

4 EQUIPMENT PHYSICAL DESCRIPTION (SKETCH, DIMENSIONS, VOLUME)

- No. req'd. - 5
- .27m x .03m x .03m = .000243m^3
- wt - 1.36kg

5 EQUIPMENT PERFORMANCE PARAMETERS (E.G , FLOW RATE, ENERGY OUTPUT, MAX TEMP., ETC)

- Operating temp. range -10°C to +5°C with accuracy $\pm$1°C.
- Separation velocity accurate up to $\pm$ 1 mm/sec
- The total b uffer and sample volumes to be handled -25 cm^3.
- Estimated power requirement 100-200 watts.
- Voltage gradient - 1 to 100 v/cm and current density 1-100 mA/cm^2

Figure II-13. TRW-Identified Separation System (Page 1 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 2

EQUIPMENT NAME	DATE
Stationary Electrophoretic Column (B 12 E)	1/2/75

6. INSTRUMENTATION: (E.G., THERMOCOUPLES, GAUGES, ETC, LOCAL & REMOTE)

- Not defined

7. SUPPORT SERVICES REQUIRED. (E.G., POWER, GASSES, VACUUM, COOLANT, OPERATOR ATTENTION)

- Power from power conditioner (5 kv).
- A regulated, controllable dc voltage supply.
- An optical monitoring system with capability of position indexing system.
- Active cooling control.
- An electrode gas elimination systme with connections to the columns.

8 EXTERNAL ENVIRONMENT REQUIRED: (E.G., ATMOSPHERE, VIBRATION LEVEL, ETC)

- None

9. EXTERNAL ENVIRONMENT PRODUCED· (E.G., EMI, HEAT, CONTAMINATION, ETC)

- None

10. SAFETY CONSIDERATIONS: (EQUIPMENT, OPERATORS, ETC)

- Electrical interlocks against electrical shocks.
- Radiation shielding for possible eye damage by radiation from the monitoring system.

11. WASTES & PRODUCTS PRODUCED

- None

Figure II-13. TRW-Identified Separation System (Page 2 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 3

EQUIPMENT NAME	DATE
Stationary Electrophoretic Columns (B 12 E)	1/2/75

12. DATA INPUT/OUTPUT REQUIREMENTS (AS EXTRACTED FROM ITEM 13)

- Input Control Functions - Maintenance of voltage gradient, column temperature, and monitoring of sample fraction separation velocities.
- Data Output - Temperaure, power input, and separation velocity.

13. FUNCTIONAL FLOW DIAGRAM (INCLUDE & NOTE AUTOMATED FUNCTIONS, DATA FLOW, CONTROL RANGES & LIMITS, ETC)

- Not defined

Figure II-13. TRW-Identified Separation System (Page 3 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 1

EQUIPMENT NAME	DATE
PH Monitor (B 15 E)	12/31/74

1. AVAILABILITY STATUS.

- ☐ NEW, REQUIRES YEARS TO DEVELOP
- ☐ MODIFICATION OF AVAILABLE EQUIP; COMPANY
- ☒ PRESENTLY AVAILABLE, COMPANY Beckman Instruments, Inc.
- ☐ SPACE QUALIFIED, PROGRAM
- ☐ OTHER

2 EXPERIMENTS ACCOMMODATED· (EXPERIMENT NAME OR TYPE)

- Biological Applications
- Chemical Processes in fluids

3 DESCRIPTION OF EQUIPMENT OPERATION (MAJOR FUNCTIONS)

- PH monitor is used to measure the acidity or alkalinity of solutions.

4 EQUIPMENT PHYSICAL DESCRIPTION (SKETCH, DIMENSIONS, VOLUME)

- No. req'd. - 1
- .37m x .46m x .30m = .051m^3
- wt - 10kg
- Metal enclosed, rack or panel mounted

5 EQUIPMENT PERFORMANCE PARAMETERS (E.G , FLOW RATE, ENERGY OUTPUT, MAX TEMP , ETC)

- Data Output - 1 bit per second
- Range - 0-12 pH units
- Spans - 2, 5, or 10 pH units
- Stability - ±0.02 pH units
- Ambient Temp. Range - -7°C to 50°C
- Liquid Temp. Range -0°C to 100°C
- Ambient Temp. Coeff. ±.002 pH/°C

Figure II-14. Typical Instrument (Page 1 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 2

EQUIPMENT NAME	DATE
PH Monitor (B 15 E)	12/31/74

6. INSTRUMENTATION: (E.G., THERMOCOUPLES, GAUGES, ETC, LOCAL & REMOTE)

- Amplifier and Indicator Units.
- Reinforcement of the control panel against acceleration and shock.
- Thermo compensator.
- Lazaran (TM) or equivalent reference electrode is used for low-g operation.

7. SUPPORT SERVICES REQUIRED: (E.G., POWER, GASSES, VACUUM, COOLANT, OPERATOR ATTENTION)

- Peak (sustained) power - 20 watts.
- Manual Temperature Condensation (if automatic control not developed)

8 EXTERNAL ENVIRONMENT REQUIRED. (E.G., ATMOSPHERE, VIBRATION LEVEL, ETC)

- None

9. EXTERNAL ENVIRONMENT PRODUCED. (E.G., EMI, HEAT, CONTAMINATION, ETC)

- None

10. SAFETY CONSIDERATIONS: (EQUIPMENT, OPERATORS, ETC)

- Meter covers are made of polycarbonate plastic instead of glass.
- No toxic or potentially flammable materials are known to be present.

11. WASTES & PRODUCTS PRODUCED

- None

Figure II-14. Typical Instrument (Page 2 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 3

EQUIPMENT NAME	DATE
PH Monitor (B 15 E)	12/31/74

12. DATA INPUT/OUTPUT REQUIREMENTS (AS EXTRACTED FROM ITEM 13)

- Input - Either 28v dc or 110v ac, 400 hz
- Output in form of a voltage shift (0-10 or 100 mV or 0-1 or 5v dc) displayed on a meter.

13. FUNCTIONAL FLOW DIAGRAM (INCLUDE & NOTE AUTOMATED FUNCTIONS, DATA FLOW, CONTROL RANGES & LIMITS, ETC)

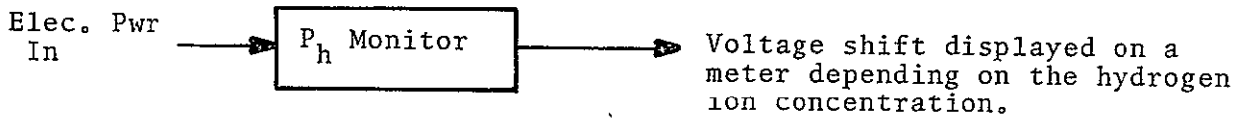


Figure II-14. Typical Instrument (Page 3 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 1

EQUIPMENT NAME	DATE
Fluid Cooling/Refrigeration Unit (B 1 E)	1/2/75

1 AVAILABILITY STATUS

- [X] NEW, REQUIRES YEARS TO DEVELOP So-Low Environmental Equipment,Co.,Inc.
- [ ] MODIFICATION OF AVAILABLE EQUIP; COMPANY
- [ ] PRESENTLY AVAILABLE; COMPANY
- [ ] SPACE QUALIFIED, PROGRAM
- [ ] OTHER

2 EXPERIMENTS ACCOMMODATED: (EXPERIMENT NAME OR TYPE)

- Biological

3 DESCRIPTION OF EQUIPMENT OPERATION (MAJOR FUNCTIONS)

- Must monitor the temperature and provide positive temperature control to the buffer and sample solutions, the stationary and continuous flow electrophoretic columns, the gas elimination systems, and the collected fractions from the continuous flow electrophoretic column.

4 EQUIPMENT PHYSICAL DESCRIPTION (SKETCH, DIMENSIONS, VOLUME)

- No. Req'd. - 1
- 1.34m x .82m x .94m = 1.033m^3
- wt - 180kg

5 EQUIPMENT PERFORMANCE PARAMETERS (E G , FLOW RATE, ENERGY OUTPUT, MAX TEMP , ETC)

- Data Output - 28 bits per second
- Temp. Range (-25°C to +45°C) with accuracy $\pm$.5°C
- Max. Heat Load to be rejected during a process run-2000 watts.

Figure II-15. Typical Refrigeration Unit (Page 1 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 2

EQUIPMENT NAME	DATE
Fluid Cooling/Refrigeration Unit (B 1 E)	1/2/75

6. INSTRUMENTATION: (E.G., THERMOCOUPLES, GAUGES, ETC, LOCAL & REMOTE)

- Temperature Sensing Device

7. SUPPORT SERVICES REQUIRED: (E G , POWER, GASSES, VACUUM, COOLANT, OPERATOR ATTENTION)

Power from 115V 60Hz supply: Peak -1592w
Sustained -746w

- The gas elimination system must be warmed to near ambient temperature in order to separate and remove the dissolved gases from buffer.
- Cooling and heating jackets
- Forced air cooling of compressor unit
- Power input cables
- Temperature sensors

8 EXTERNAL ENVIRONMENT REQUIRED (E G , ATMOSPHERE, VIBRATION LEVEL, ETC)

- None

9 EXTERNAL ENVIRONMENT PRODUCED. (E G , EMI, HEAT, CONTAMINATION, ETC)

- EMI Generation during compressor start up.

10. SAFETY CONSIDERATIONS (EQUIPMENT, OPERATORS, ETC)

- Guarded against fluid spillage
- Any glass cover can be replaced by polycarbonate plastic
- The refrigerant should not be inflammable at operating environment

11. WASTES & PRODUCTS PRODUCED

- None

Figure II-15. Typical Refrigeration Unit (Page 2 of 3)

PAYLOAD EQUIPMENT DEFINITION DATA - SHEET 3

EQUIPMENT NAME	DATE
Fluid Cooling/Refrigeration Unit (B 1 E)	1/2/75

12. DATA INPUT/OUTPUT REQUIREMENTS (AS EXTRACTED FROM ITEM 13)

- The input control functions - Temperature monitoring and provide sufficient flow rate of the coolant fluid to maintain the desired temperature.
- Data output - Temperatures, and flow rate

13 FUNCTIONAL FLOW DIAGRAM (INCLUDE & NOTE AUTOMATED FUNCTIONS, DATA FLOW, CONTROL RANGES & LIMITS, ETC)

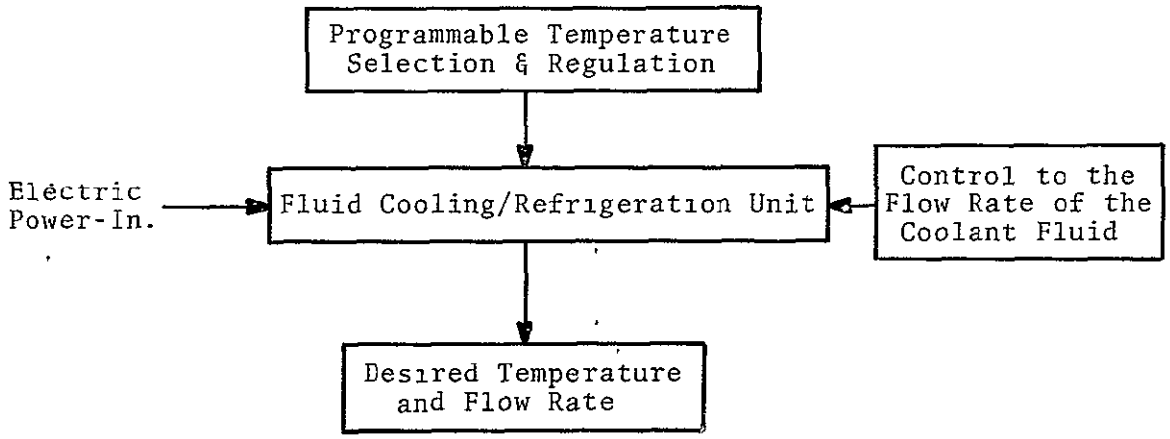
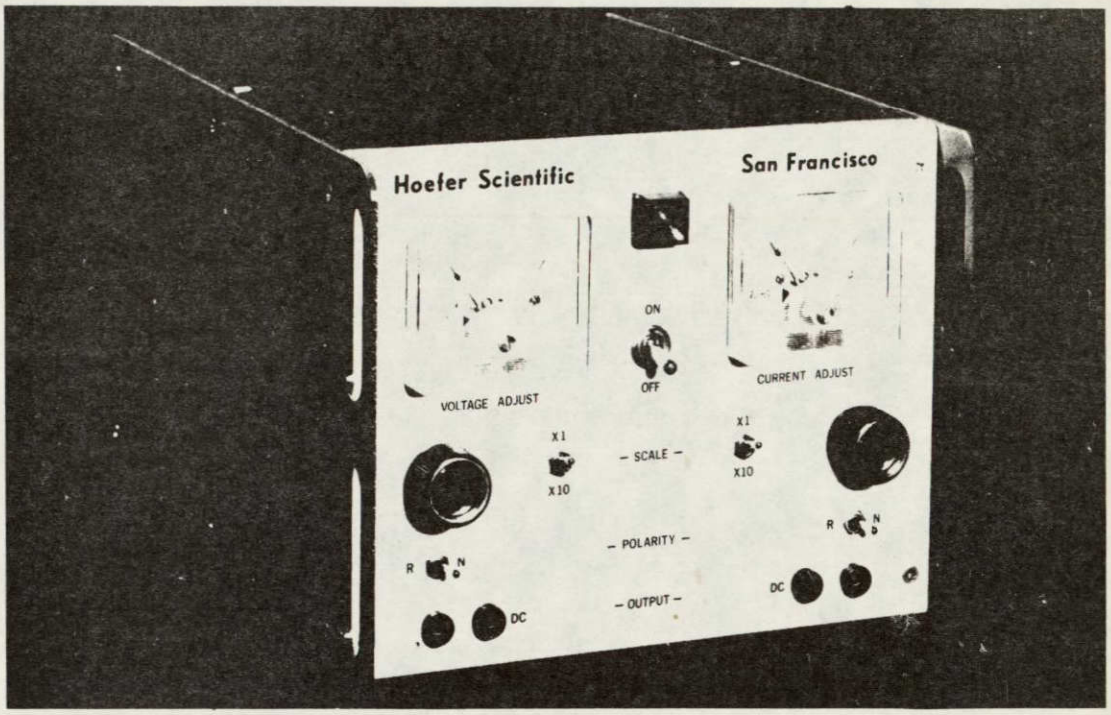


Figure II-15. Typical Refrigeration Unit (Page 3 of 3)

HOEFER SCIENTIFIC INSTRUMENTS

D.C. power supply

Micro-Analytical Instruments For Biochemical Research



A COMPACT, SOLID STATE POWER SUPPLY DESIGNED FOR GEL ELECTROPHORESIS

Design

All-silicon solid state components insure dependable power in the lab or the cold room.

Circuit design offers full protection against short circuit damage.

Taut-band meters are durable and can be read easily.

Handles are incorporated in the case design to make the unit easily portable. They also provide special protection for the control panel.

Function

The current and voltage have separate controls and separate meters. This dual arrangement eliminates awkward switching back and forth imposed by single-meter models. A ten-turn potentiometer makes adjusting the current easy and accurate.

Two pairs of output terminals enable the operator to use two electrophoresis cells simultaneously. Each pair of output terminals has a polarity reversing switch. There is no need to reverse the leads.

Scale selection switches enable the operator to read low currents and voltages with full scale accuracy. This is especially useful in operations which use less than one milliamp of current per tube.

Specifications

Constant voltage: 0 to 400 VDC

Constant current: 0 to 80 ma

Load regulation: ±0.15%

Line regulation: ±0.2%

Ripple rejection: 74db

Ordering Information

PS 101 DC Power Supply 0-400 VDC, 0-80 ma; constant current, constant voltage

Shipping Weight: 20 lbs. **Price: $350.00**

HOEFER SCIENTIFIC INSTRUMENTS • 520 Bryant Street, San Francisco, California 94107 • (415) 398-1642

Figure II-16. Typical Power Supply

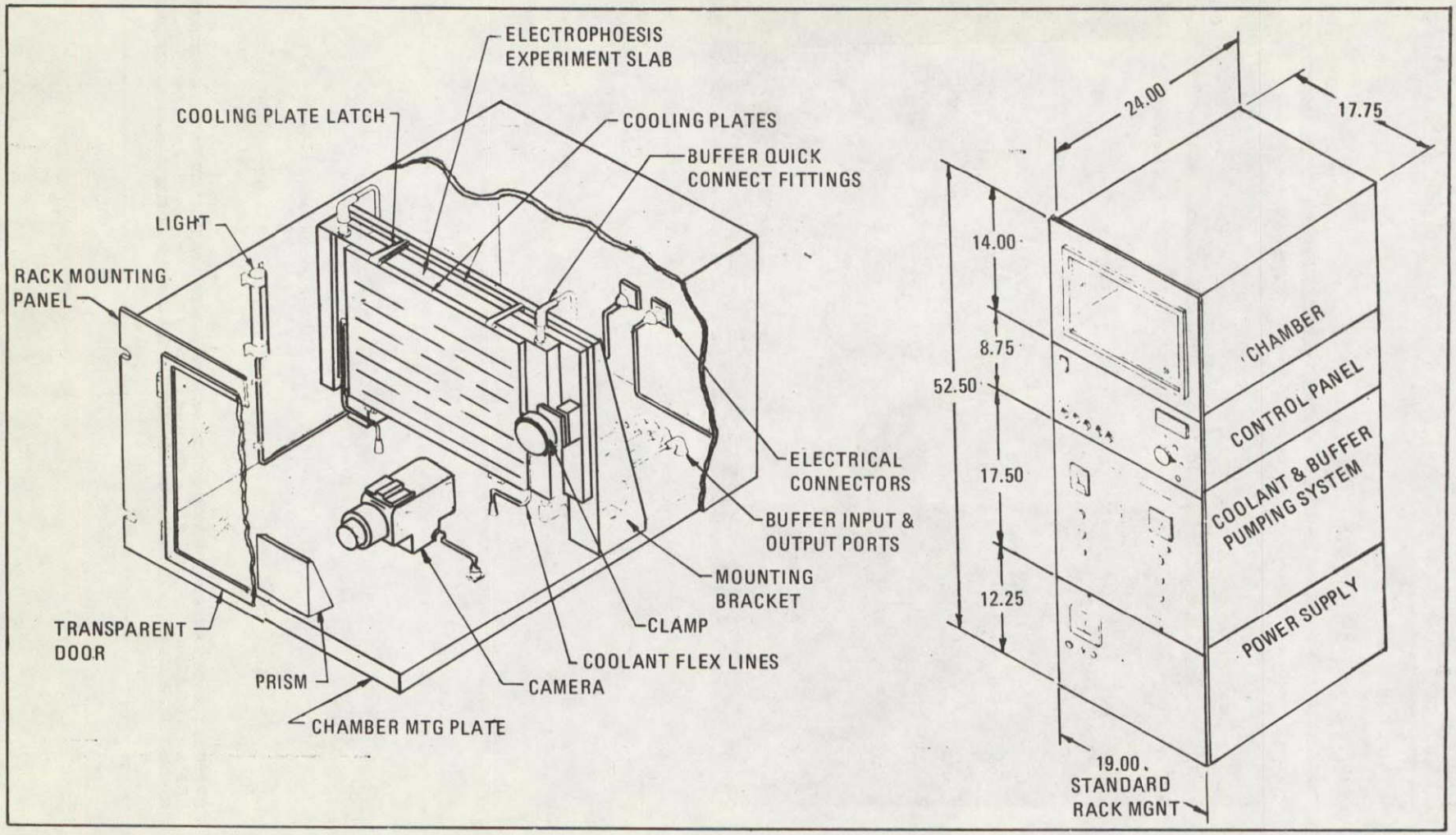


Figure II-17. Shuttle/Space Lab Gel Electrophoresis Experiment

Item	Space Development Required?	Quantity Required Initial (Ground Test)	Quantity Required Prototype	Quantity Required Pilot	Quantity Required Production
Analytical 12 Col Electrophoresis Separator	Yes	1	–	–	–
Preparative 1-Col. Separator	Yes	1	1	1	2
Power Supply, Electrophoresis	Yes	1	1	1	2
Cooling Bath (Circulating) & Pump	Yes	1	1	1	2
Copying Camera	No	1	1	1	–
Storage Refrigerator	Yes	1	1	1	1
Deep Freeze	Yes	1	1	1	1
Freeze Drying Unit	Yes	1	1	1	–
Vacuum Pump	No	1	1	1	1
Circulating Hot Water Bath	Yes	1	1	1	1
Thermocouples & Meters	No	1 set	1	1	1
Gas Chromatograph	No	1	1	–	–
Centrifuge (Clinical)	No	1	–	–	–
Homogenizer	No	1	–	–	–
Microscope	No	1	–	–	–
UV Spectrophotometer	No	1	–	–	–
Fraction Collector	Yes	1	1	1	1

Figure II-18. Development Equipment List

Requirement	Equipment or Operational Need
Safety	
• Temperature	- No crew or mission hazard
• Toxic or Corrosive Mat'l	- Buffer fluids are corrosive. Positive seals, purging required for repetitive batch operations.
• High Voltage	- Up to 1300 volts possible. Standard electrical safety fusing and grounding required.
Waste Control	
• Gas, Liquid, Solid	- All gel electrophoresis products are contained in gel tube. (If decision to form gel in orbit is made, evolving gases must be collected.)
• Heat	- Ohmic heating must be extracted.
Sterility	- Critical requirements. All process equipment must be prepackaged sterile. Fresh equipment for each new material, or lab grade sterilization procedure and equipment must be provided.

Figure II-19. Special Requirements for Space Processing of Isoenzymes

- antiserum preparation in animals
- extraction of antiserums and preparation of gamma globulin fractions
- preparation of kits for use by clinicians (final product)

The functions involved are conventional and therefore the development effort will be concerned with establishment of specific equipment and techniques and accommodation of throughput requirements. For example, animals used for antiserum preparation might be rabbits or goats, but throughput considerations suggest the use of larger animals such as horses. A throughput on the order of one million kits per year would

require maintenance of perhaps 100 horses or more, depending on the number of different antigens processed. The testing of experimental kits with humans, which would be necessary before commitment to preparative scale operations, must also be addressed. This testing, as well as the final product, would be based on a diagnostic kit (one per patient) with a separate kit required for each disease to be diagnosed, such as a particular type of cancer. The ultimate objective for a given kit would be to achieve 90-95% effectiveness in diagnosis that a disease is present, and an equivalent effectiveness in diagnosing that a disease is not present. Arrangement of tests for diagnostic kits will be established with hospitals or clinics during the ground lab test phase, to obtain preliminary, relatively crude indications of antigen effectiveness. These indications will then form the basis for zero-G tests of particular isoenzymes separations, and further antigen tests.

A series of laboratory tests and clinical trials will be performed to determine first indications of antibody efficacy based on best ground-based methods. About 10 antibody/antigen systems will be examined. These findings will form the basis for in-space processing of the most promising isoenzymes. The laboratory tests will consist of complement fixation testing to determine the amount of antibody obtained, and immuno-diffusion testing to determine the purity of the antibody samples. The clinical trials will be conducted with volunteer patients and collaborating physicians. The patients will be high-risk candidates where perhaps 10% of the patients actually have the disease being diagnosed. After patient diagnosis, a follow-up study of each patient (about one year) will be conducted to determine whether the diagnosis gave false positive or false negative indications.

Following the ground-based tests, a similar series of tests will be conducted to compare the space-processed product with the earlier ground-processed product results. The findings of this comparison will form the basis for on-going space processing.

When pilot plant and full-scale production activities are instituted, routine evaluation of space-processed products will be necessary as a quality control measure. The method for this evaluation will be essentially the same as described above for the development program.

II.3 DEVELOPMENT SCHEDULE

The development schedule, Figure II-20 indicates the emphasis to be placed on investigation of the phenomenological questions which must be answered for the large pore gel electrophoresis separation process. These activities (WBS 5.0) will address the enzyme mobility, convection, path length and other topics initially in a ground laboratory environment in the period 1975-1977. Apparatus requirements are expected to evolve as the phenomena become understood, so that the equipment designed for zero-G operation in sounding rocket tests and later shuttle tests should need relatively few design modifications as the result of flight tests. The number of flights shown presumes successful anticipation of zero-G requirements during the ground laboratory test phases.

The point at which a business decision can be made to proceed into the pilot/production phase is undetermined, but presumably would occur about 1981, when the first results of shuttle-based experiments are known and the first isoenzyme samples have been tested. This timing would allow an orderly preparation for full scale production which would be achieved about 1985. The financial forecast assumed small scale production and initial sales in 1982, which presumes that a small pilot capacity is established in that year, with at least one successful isoenzyme isolation having acceptable product efficiency.

The time available between 1975 and the shuttle availability allows an adequate period for accomplishment of the required research and development work. However, the crucial nature of the information to be gotten from the phenomenological investigations

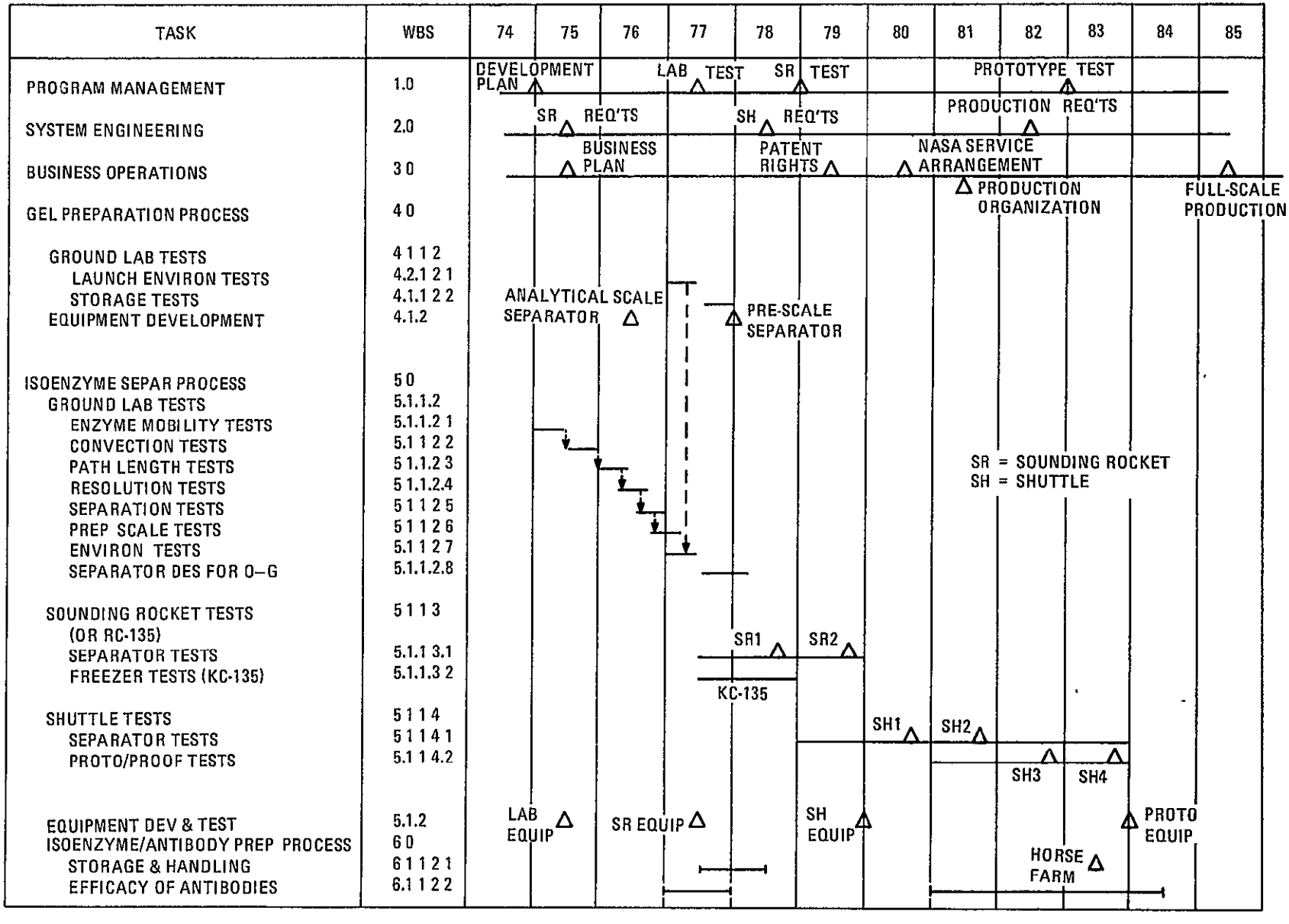


Figure II-20. Isoenzyme Processing Development

suggests that this work be accomplished as soon as possible, to confirm the feasibility or non-feasibility of the product concept. A key activity for making this determination is that for testing the efficacy of antibodies (WBS 6.1.1.2.2) wherein the sample antigens obtained from ground laboratory and in-space separations will be tested in clinical situations to obtain first confidence in isoenzyme selection, and to determine diagnostic capabilities of the samples.

SECTION III

RESOURCES PLANNING

As in the preceding section, which extracted the program activities, their key milestones and timing, from the documented Work Elements in order to provide development Planning data, we also analyzed the Resource Requirements and Resource Costs documents to extract the Resource Planning data.

Based on these requirements and costs, we have delineated the planned allocation of development costs for the Isoenzyme program under study. For programmatic purpose these allocations have been assembled under several combinations of categories: type of resource, WBS elements, timing, and for both Case A and Case B.

A summary of the estimated costs for Case A, broken down by major resource category, is shown in Figure III-1A for each major WBS Element and in figure III -1B for lower level WBS Elements. The $3.8 million total program cost includes the cost of Sounding Rocket Motors and NASA service charges for Sounding Rocket, KC-135 and Shuttle flights in the R&D phase.

A time-phased statement of those same costs for Case A is given in Figure III-2, broken down to the lower levels of WBS elements.

Case B costs for R&D (wherein the User does not bear the proof-of-process-feasibility costs) are shown in Figure III-3.

It is important to recognize that costs are, in some cases, only measures of resources such as personnel with key skills, facilities, special equipment, etc. A tabulation of such resources by WBS element is shown in Figure III-4.

WBS	Work Element Task	Labor Cost	Purchased Materials Cost	Services Cost	Equipment Cost	Facilities Cost	Total Cost	Time Period
1.1	Program Management	-	-	347K	-	-	347K	75-83
2.1	System Engineering	-	-	316K	-	-	316K	75-83
3.1	Business Operations	-	-	-	-	-	-	75 onward
4.1	Gel Preparation Process	37K	1K	26K	2K	-	66K	1977
5.1	Separation Process	837K	469K	1552K	208K	-	3066K	75-83
6.1	Antibody Prep. Process	11K	1K	12K	-	-	24K	77-83
	TOTALS	885K	471K	2253K	210K	-	3819K	

Figure III-1A. Isoenzymes Research & Development Program Cost Summary-Case A

WBS	Work Element Task	Labor Cost	Purchased Materials Cost	Services Cost	Equipment Cost	Facilities Cost	Total Cost	Time Period
1.1	Program Management	--	--	347K	--	--	347K	75-83
2.1	System Engineering	--	--	316K	--	--	316K	75-83
3.1	Business Operations	--	--	--	--	--	--	--
4.1	Gel Preparation Process	37.0K	1.4K	25.6K	2.0K	--	66.0K	1977
4.1.1	Process Development	37.0K	1.4K	25.6K	7.0K	--	66.0K	1977
4.1.1.1	Project Supervision	6.0K	--	--	--	--	6.0K	1977
4.1.1.2	Ground Lab Tests	31.0K	1.4K	25.6K	2.0K	--	60.0K	1977
4.1.1.2.1	Launch Environ Tests	10.3K	0.7K	25.6K	2.0K	--	38.6K	1Q77
4.1.1.2.2	Storage Tests	20.7K	0.7K	--	--	--	21.4K	2H77
4.1.2	Equipment Development	--	--	--	--	--	--	1977
5.1	Separation Process	837K	468.5K	1551.9K	208.3K	--	3065.7K	75-83
5.1.1	Process Development	533K	368.5K	1551.9K	158.3K	--	2611.7K	75-83
5.1.1.1	Project Supervision	237K	--	--	--	--	237K	75-83
5.1.1.2	Ground Lab Tests	121.4K	25.0K	174.4K	14.3K	--	335.1K	75-78
5.1.1.2.1	Enzyme Mobility Tests	8.8K	0.5K	--	1.8K	--	11.1K	1H75
5.1.1.2.2	Convection Tests	35.6K	0.5K	--	0.6K	--	36.7K	2H75
5.1.1.2.3	Path Length Tests	9.0K	0.8K	0.6K	--	--	10.4K	1Q76
5.1.1.2.4	Path Length Isoelec. Tests	8.8K	0.6K	--	--	--	9.4K	2Q76
5.1.1.2.5	Best Ground Method Tests	39.4K	1.6K	3.8K	6.8K	--	51.6K	1H76
5.1.1.2.6	Preparative Scale Tests	10.0K	0.6K	1.4K	1.0K	--	13.0K	3Q76
5.1.1.2.7	Environmental Tests	3.4K	0.1K	70.0K	4.1K	--	77.6K	2Q77
5.1.1.2.8	O-G Separator Tests	6.4K	20.3K	98.6K	--	--	125.3K	1978
5.1.1.3	Sounding Rocket Tests	22.6K	315.5K	472.5K	--	--	810.6K	78-79
5.1.1.3.1	Separator Tests	20.0K	312.0K	446.0K	--	--	778.0K	78-79
5.1.1.3.2	Freezer Tests (KC135)	2.6K	3.5K	26.5K	--	--	32.6K	78-79
5.1.1.4	Shuttle Tests	152.0K	28.0K	905K	144.0K	--	1229K	79-83
5.1.1.4.1	Shuttle Test-Dev.	50.0K	10.0K	385K	72.0K	--	517K	79-82
5.1.1.4.2	Shuttle Test-Proto/Proof	102.0K	18.0K	520K	72.0K	--	712K	82-83
5.1.2	Equipment Development	304.0K	100.0K	--	50.0K	--	454K	75-78
6.1	Antibody Prep. Process	11.2K	0.7K	12.0K	--	--	23.9K	77-83
6.1.1	Process Development	11.2K	0.7K	12.0K	--	--	23.9K	77-83
6.1.1.1	Project Supervision	2.2K	--	--	--	--	2.2K	77-83
6.1.1.2	Ground Lab Tests	9.0K	0.7K	12.0K	--	--	21.7K	77-83
6.1.1.2.1	Storage Tests	5.6K	0.2K	--	--	--	5.8K	2Q77
6.1.1.2.2	Antibody Effectiveness Tests	3.4K	0.5K	12.0K	--	--	15.9K	77-83
6.1.2	Equipment Development	--	--	--	--	--	--	--

Figure III-1B. Detailed Isoenzymes Research & Development Program Cost-Case A

WBS	Task	Total Cost	75	76	77	78	79	80	81	82	83
1.1	Program Management	347K	12K	16K	23K	76K	69K	32K	54K	39K	26K
2.1	System Engineering	316K	11K	14K	21K	69K	63K	29K	49K	36K	24K
3.1	Business Operations	--	--	--	--	--	--	--	--	--	--
4.1	Gel Preparation Process	66K	--	--	66K	--	--	--	--	--	--
5.1	Separation Process	3066K	107K	143K	135K	695K	659K	278K	463K	349K	237K
6.1	Antibody Prep. Process	24K	--	--	--	--	5K	4K	5K	4K	--
	TOTALS	3819K	130K	173K	251K	840K	796K	343K	571K	428K	287K

Figure III-2A. Isoenzymes Research and Development Program (By Year) Summary - Case A

WBS	Task	Total Cost	75	76	77	78	79	80	81	82	83
1.1	PROGRAM MANAGEMENT	347K	12.0K	16.0K	23.0K	76.0K	69.0K	32.0K	54.0K	39.0K	26.0K
2.1	SYSTEM ENGINEERING	316K	11.0K	14.0K	21.0K	69.0K	63.0K	29.0K	49.0K	36.0K	24.0K
3.1	BUSINESS OPERATIONS	--	--	--	--	--	--	--	--	--	--
4.1	GEL PREPARATION PROCESS	66.0K	--	--	66.0K	--	--	--	--	--	--
4.1.1	Process Development	66.0K	--	--	66.0K	--	--	--	--	--	--
4.1.1.1	Project Supervision	6.0K	--	--	6.0K	--	--	--	--	--	--
4.1.1.2	Ground Lab Tests	60.0K	--	--	60.0K	--	--	--	--	--	--
4.1.1.2.1	Launch Environment Tests	38.6K	--	--	38.6K	--	--	--	--	--	--
4.1.1.2.2	Storage Tests	21.4K	--	--	21.4K	--	--	--	--	--	--
4.1.2	EQUIPMENT DEVELOPMENT	--	--	--	--	--	--	--	--	--	--
5.1	SEPARATION PROCESS	3065.7K	106.6K	142.9K	135.4K	694.6K	659.1K	278.0K	463.1K	348.5K	237.5K
5.1.1	Process Development	2611.7K	52.6K	92.9K	85.4K	644.6K	609.1K	228.0K	413.1K	298.5K	187.5K
5.1.1.1	Project Supervision	237.0K	4.8K	8.5K	7.8K	58.7K	52.1K	21.0K	39.1K	27.5K	17.5K
5.1.1.2	Ground Lab Tests	335.1K	47.8K	84.4K	77.6K	125.3K	--	--	--	--	--
5.1.1.2.1	Enzyme Mobility Tests	11.1K	11.1K	--	--	--	--	--	--	--	--
5.1.1.2.2	Connection Tests	36.7K	36.7K	--	--	--	--	--	--	--	--
5.1.1.2.3	Path Length Tests	10.4K	--	10.4K	--	--	--	--	--	--	--
5.1.1.2.4	Path Length-Isoelectric Tests	9.4K	--	9.4	--	--	--	--	--	--	--
5.1.1.2.5	Best Ground Method Tests	51.6K	--	51.6K	--	--	--	--	--	--	--
5.1.1.2.6	Preparative Scale Tests	13.0K	--	13.0K	--	--	--	--	--	--	--
5.1.1.2.7	Environmental Tests	77.6K	--	77.6K	--	--	--	--	--	--	--
5.1.1.2.8	O-G Separator Tests	125.3K	--	--	--	125.3K	--	--	--	--	--
5.1.1.3	Sounding Rocket Tests	810.6K	--	--	--	460.6K	350.0K	--	--	--	--
5.1.1.3.1	Separator Test	778.0K	--	--	--	428.0K	350.0K	--	--	--	--
5.1.1.3.2	Freezer Test (KC-135)	32.6K	--	--	--	32.6K	--	--	--	--	--
5.1.1.4	Shuttle Tests	1229.0K	--	--	--	--	207.0K	207.0K	374.0K	271.0K	170.0K
5.1.1.4.1	Shuttle Tests-Dev.	517.0K	--	--	--	--	207.0K	207.0K	103K	--	--
5.1.1.4.2	Shuttle Tests-Prots/Proof	712.0K	--	--	--	--	--	--	271.0K	271.0K	170.0K
5.1.2	Equipment Development	454.0K	54.0K	50.0K	50.0K	50.0K	50.0K	50.0K	50.0K	50.0K	50.0K
6.1	ANTIBODY PREP. PROCESS	23.9K	--	--	6.4K	--	4.4K	4.4K	4.4K	4.8K	--
6.1.1	Process Development	23.9K	--	--	6.4K	--	4.4K	4.4K	4.4K	4.3K	--
6.1.1.1	Project Supervision	2.2K	--	--	0.6K	--	0.4K	0.4K	0.4K	0.4K	
6.1.1 2	Ground Lab Tests	21.7K	--	--	5.8K	--	4.0K	4.0K	4.0K	3.9K	--
6.1.1.2.1	Storage Tests	5.8K	--	--	5.8K	--	--	--	--	--	--
6.1.1.2.2	Antibody Effectiveness Tests	15.9K	--	--	--	--	4.0K	4.0K	4.0K	3.9K	
6.1.2	Equipment Development	--	--	--	--	--	--	--	--	--	

Figure III-2B. Detailed Isoenzymes Research and Development Program Cost (By Year) - Case A

(Excludes all tasks associated with establishing process feasibility)

Cubs	Task	Total Cost	75	76	77	78	78	80	81	82	83
1.1	Program Management	125 0K						6.0K	54.0K	39.0K	26.0K
2.1	System Engineering	114.0K						5.0K	49.0K	36.0K	24.0K
3 1	Business Operations	-	-	-	-	-	-	-	-	-	-
4.1	Gel Prep.	-	-	-	-	-	-	-	-	-	-
5.1	Separation Process	1104.1K	-	-	-	-	-	55.0K	463.1K	348.5K	237.5K
5.1.1	Process Dev.	904.1K						5.0K	413.1K	298.5K	187.5K
5.1.1.1	Project Supervision	89.1K	-	-	-	-	-	5.0K	39.1K	27.5K	17.5K
5.1.1.2		-									
5.1.1.2.1		-									
5.1.1.2.2		-									
5.1.1.2.3		-									
5.1.1.2.4		-									
5.1.1.2.5		-									
5.1.1.2.6		-									
5.1.1.2.7		-									
5.1.1.2.8		-									
5.1.1.3		-									
5.1.1.3.1		-									
5.1.1.3.2		-									
5.1.1.4	Shuttle Tests	815 0K	-	-	-	-	-	-	374.0K	271.0K	170.0K
5.1.1.4.1	Shuttle Tests - Dev.	103 0K	-	-	-	-	-	-	103.0K	-	-
5.1.1.4.2	Shuttle Tests - Proto/Proof	712.0K							271.0K	271.0K	170.0K
5.1.2	Equipment Dev.	200.0K	-	-	-	-	-	50.0K	50.0K	50.0K	50.0K
6.1	Antibody Prep. Process	8 7K	-	-	-	-	-	-	4.4K	4.3K	-
6.1.1	Process Dev.	8.7K							4.4K	4.3K	-
6.1.1.1	Project Supervision	0.8K							0.4K	0.4K	-
6.1.1.2	Ground Lab Tests	7 9K							4.0K	3.9K	-
6.1.1.2.1	Storage Tests	-	-	-	-	-	-	-	-	-	-
6.1.1.2.2	Antibody Effectiveness Tests	7.9K	-	-	-	-	-	-	4.0K	3.9K	-
6.1.2	Equip. Dev.	-	-	-	-	-	-	-	-	-	-
	TOTALS	1351.8K	-	-	-	-	-	66.0K	570.5K	427.8K	287.5K

Figure III-3. User Isoenzymes R&D Program Costs - Case B
(Where NASA Establishes Process Feasibility)

Cubs	Task	Period (Years)	Special Skills	Materials	Services	Equipment	Facilities
1.1	Program Management	75 - 83	Aerospace/Commercial Experience	-	Aerospace contractor/ integrator	N/A	Conventional
2.1	System Engineering	75 - 83	Aerospace/Commercial Experience	-	Aerospace contractor/ integrator	N/A	Conventional
3.1	Business Operations	75 onward	-	-	Market research	N/A	Conventional
4.1	Gel Preparation Process	77					
4.1.1	Process Development	77	Biochemist Bio-lab technicians	Gels, tubes, reagents, substrates, photo supplies, glassware, stains	Vibration and shock test, Centrifuge tests (Johnsville)	Electrophoresis apparatus storage equipment, Gel tube filling equipment	Biological Lab Vibration and shock test facility, Johnsville centrifuge
4.1.2	Equipment Development	75 - 83	Biochemist Bio-lab technicians	same as 4.1.1	same as 4 1 1	same as 4.1.1	same as 4.1.1
5.1	Separation Process				Vibration and shock	Electrophoresis apparatus	Biological Lab
5.1.1	Process Development	75 - 83			tests, Centrifuge	(analytical and preparative)	Vibration and Shock Test
5 1.1.2	Ground Lab Tests	75 - 78	Biochemist Bio-lab technicians Biological equipment design Aerospace payload design	same as 4 1.1, plus tissue and sera	tests (Johnsville), Glass blowing, Literature search Pathologist Clinician Equipment design and fabrication		Facility, Johnesville centrifuge
5.1.1.3	Sounding Rocket Tests	78 - 79	same as 5.1.1 2	same as 5.1.1.2 plus payload equip materials, sounding rocket motors	Sounding Rocket payload design and fabrication Sounding Rocket launch and payload recovery	same as 5.1.1.2	Payload fabrication and test facilities, Sounding Rocket launch and recovery facilities, Biological Lab.
5.1.1 4	Shuttle Tests	79 - 83	same as 5 1.1.2	same as 5.1.1.2 plus payload equipment materials	Shuttle payload design and fabrication, Shuttle launch and return services	same as 5.1.1.2	Payload fabrication and test facilities, Biological Lab, Shuttle launch and return facilities
5.1.2	Equipment Development	75 - 73	same as 5 1 1 2	same as 5.1.1.1	Shuttle payload design and fabrication	same as 5.1.1.2	Payload fabrication and test facilities Biological Lab
6.1	Antibody Preparation Process	77 - 82					
6 1.1	Process Development	77 - 82					
6 1.1.2	Ground Lab Tests	77 - 82	same as 4.1.1	same as 5.1 1 2	Cooperating physicians and clinics Cooperating patient volunteers	Electrophoresis apparatus Freezer equipment Assay equipment	Biological Lab
6 1 2	Fquipment Development	77 - 82	same as 6 1.1.2	same as 5.1.1.2	None	same as 6.1.1.2	Biological Lab

Figure III-4. Isoenzymes Resources Requirements (R&D) Summary

SECTION IV

CASH FLOW ANALYSIS

The data inputs and parameter values used in the baseline cash flow analysis are shown in Figure IV-1. The financial forecast for Case A for the period 1975 to 1992 is presented in Figure IV-2 A&B. A total market climbing to 50,000,000 units per year was estimated, with a relatively small market share reaching 10%, on the basis that the business would not attempt to address a large share of the market of that size, at least initially. The unit price starts out relatively high, but feasible, and reduces over time to $6. Lower unit prices in later years appear feasible, judging from the very good performance indicators. The Case B forecast is given in Figures IV-3 and IV-4 A & B.

A User-funded research and development program of about $1.4 million (Case B) is estimated as required to establish a production capability after demonstration of process feasibility.

Various iterations of throughput and approach were tried in order to establish a baseline process which could produce a diagnostic kit for a unit price of $15 initially, with an objective of reduction to $6 per kit after wide-scale application of the method.

Financial analysis was based on estimation of the following 6 items over a time period from 1975 through 1992:

Total Market - demand for diagnostic kits in the United States, based on the assumed existence of 10 relatively high incidence diseases amenable to the proposed method of diagnosis.

Market Share - per cent of total market to be satisfied by the producer, based on a gradual buildup to 10% of total market over the time period.

Unit Price - based on a relatively high initial kit price which is reduced to a price near present-day prices for kits of a similar nature.

Unit Manufacturing Cost - based on an itemization of the process costs to produce diagnostic kits, including ground gel tube preparation, in-space processing, space charges, ground antibody generation (via horse farm) and kit packaging.

Research and Development Cost - based on an estimate of the ground lab and space shuttle/spacelab experiments required to achieve a prototype process capability. Case A includes full R&D costs, while Case B excludes the costs of demonstrating process feasibility.

Annual Plant and Equipment - based on equipment and plant expansion or addition required. A ten-year straight line depreciation was used for purposes of simplicity.

A simplified financial forecast routine was then used to determine the following business venture performance measures:

Percent Return on Investment (ROI)

This is calculated as annual net profit (after taxes and before payment of dividends) divided by net annual investment. The significance of the Return on investment is that it indicates the yield to the business after all costs are deducted. It can be

compared on an annual basis to the return which might be obtained from alternate investment of the same funds, including the option of putting the money in a bank savings account. The baseline (Case B) ROI obtained is 73% (1992) which is very high and suggests that actual results would be lower based on a higher investment or lower profit margin due to competitors entering the market.

Percent Net Income to Sales

This is calculated as net profit (after taxes and before payment of dividends) divided by annual sales. The significance of the Net Income to Sales percent is that it indicates the yield relative to the amount of business (sales) being conducted, for comparison with what yield that type of business normally expects to achieve. The figure obtained is 21% (Case B) which is well above the pharmaceutical industry figure of 9.1% (in 1972).

Cumulative Cash Flow

This is the summation of the annual amounts of money which must be put into (or can be taken out of) the business over the forecast period. Annual cash flows are determined as the annual net income after taxes less the annual net change in investment. The summation of the annual cash flows over time gives the cumulative cash flow. In general, the sooner that a business can generate positive cash flow (excess cash), the more attractive the venture. In the years when annual cash flow is positive, the business is generating more cash than is needed to operate the business. At the time when cumulative cash flow turns positive, the business will have paid back all of the money put into the business up to that point (breakeven period). The cumulative cash flow for Case B turns positive in 1985, 7 years after first expenditures, which is an acceptable indicator, considering the long term prospects of the Case B venture.

Present Value

Present value is a measure of the worth today of funds expected to be paid out or received in the future based on a chosen discount rate. The present value of the business

is calculated by discounting the annual cash flow at a rate of 10 percent. The net annual investment in the last year of the forecast period, which can be taken as a measure of the liquidation value of the business, was included in the calculation. The baseline present value for Case B is: plus $12M. The significance of the Present Value measure is that at zero present value, a businessman is indifferent (theoretically) as to whether he puts his money in the bank at interest (at the assumed discount rate), or into the business (disregarding business risk). For a positive present value, he would rather put his money into the business.

Constants were established for calculation of costs other than those inputted as shown in Figure IV-1 and IV-3. Space charges based on the BUS Phase III cost model were included in R&D and production costs.

The relatively compact, low weight, low energy consumption characteristics of the isoenzyme electrophoretic separation facility make it relatively insensitive to space charges compared to other products studied.

Changes in assumptions could be made to reduce the attractiveness (or increase the conservativeness) of this conceptual venture:

Decrease unit price

Increase unit manufacturing cost

Increase other operating expenses

Decrease market share

Increase investment

On the optimistic side, assuming the total market is valid, the market share is very conservative. An increase in market share would improve overall venture attractiveness.

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INPUTS:	75	76	77	78	79	80	81	82	83	84
TOTAL MARKET (UNITS)	0.	0.	0.	0.	0.	20000000.	20000000.	20000000.	20000000.	20000000.
MARKET SHARE (PCT)	0.	0.	0.	0.	0.	0.	0.	2.	4.	5.
UNIT PRICE	0.	0.	0.	0.	0.	0.	0.	15.	15.	15.
UNIT MANUFACTURING COST	.00	.00	.00	.00	.00	.00	.00	6.00	6.00	6.00
R AND D EXPENSE	130000.	173000.	231000.	840000.	796000.	343000.	571000.	428000.	287000.	0.
ANNUAL PLANT AND EQUIP.	0.	0.	0.	0.	750000.	600000.	980000.	0.	0.	1280000.

INPUTS:	85	86	87	88	89	90	91	92	93	94
TOTAL MARKET (UNITS)	25000000.	30000000.	35000000.	40000000.	45000000.	50000000.	50000000.	0.	0.	
MARKET SHARE (PCT)	6.	6.	7.	7.	8.	8.	8.	10.	0.	0.
UNIT PRICE	15.	15.	14.	13.	10.	9.	8.	6.	0.	0.
UNIT MANUFACTURING COST	5.30	5.30	5.30	5.30	4.50	4.00	3.00	2.50	.00	.00
R AND D EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
ANNUAL PLANT AND EQUIP.	850000.	500000.	0.	1480000.	500000.	0.	0.	0.	0.	0.

PARAMETRIC PERCENTAGES:

PARAMETER	IDENTIFIER	VALUE	PARAMETER	IDENTIFIER	VALUE
INTEREST RATE	P11	10.00	UNITS MANUFACTURED PCT.	P21	120.00
AVERAGE INVENTORY PCT.	P23	20.00	ENGINEERING EXPENSE PCT.	P26	5.00
SELLING EXPENSE PCT.	P27	5.00	ADMINISTRATION EXPENSE PCT	P28	10.00
RECEIVABLES PCT.	P31	20.00	DEPRECIATION PERIOD(YRS)	P35	10.00
OTHER INVESTMENT PCT.	P36	5.00			

PERCENTAGE OF BASELINE USED INPUTS	IDENTIFIER	PCT
TOTAL MARKET	X1	100
MARKET SHARE	X2	100
UNIT PRICE	X3	100
UNIT MANUFACTURING COST	X4	100
R AND D EXPENSE	X5	100
ANNUAL PLANT AND EQUIP.	X6	100

ADD/SUB FROM BASELINE INPUTS IDENTIFIER	VALUE
A1	0.
A2	0.
A3	.00
A4	0.
A5	0.
A6	0.

Figure IV-1. Isoenzymes Input Values - Case A

8/6/75

	75	76	77	78	79	80	81	82	83	84
TOTAL MARKET (UNITS)	0.	0.	0.	0.	0.	20000000.	20000000.	20000000.	20000000.	20000000.
MARKET SHARE (PCT)	.00	.00	.00	.00	.00	.00	.00	2.00	4.00	5.00
UNITS SOLD (UNITS)	0.	0.	0.	0.	0.	0.	0.	400000.	800000.	1000000.
UNIT PRICE	0.	0.	0.	0.	0.	0.	0.	15.	15.	15.
SALES	0.	0.	0.	0.	0.	0.	0.	6000000.	12000000.	15000000.
OPERATING EXPENSES	130000.	173000.	251000.	840000.	871000.	478000.	804000.	4273000.	7744000.	9391000.
GROSS PROFITS	-130000.	-173000.	-251000.	-840000.	-871000.	-478000.	-804000.	1727000.	4256000.	5609000.
ANNUAL INVESTMENT	0.	0.	0.	0.	675000.	1140000.	1887000.	3130000.	4373000.	6030000.
CUMULATIVE GROSS PROFITS	-130000.	-303000.	-554000.	-1394000.	-2265000.	-2743000.	-3547000.	-1820000.	2436000.	8045000.
BASE FOR INTEREST EXP.	130000.	303000.	554000.	1394000.	2940000.	3883000.	5434000.	4950000.	1937000.	0.
INTEREST EXPENSE	13000.	30300.	55400.	139400.	294000.	388300.	543400.	495000.	193700.	0.
INCOME BEFORE TAXES	-143000.	-203300.	-306400.	-979400.	-1165000.	-866300.	-1347400.	1232000.	4062300.	5609000.
TAXES	-68640.	-97584.	-147072.	-470112.	-559200.	-415824.	-646752.	591360.	1949904.	2692320.
NET INCOME AFTER TAXES	-74360.	-105716.	-159328.	-509288.	-605800.	-450476.	-700648.	640640.	2112396.	2916680.
NET CHANGE IN INVEST.	0.	0.	0.	0.	675000.	465000.	747000.	1243000.	1243000.	1657000.
ANNUAL CASH FLOW	-74360.	-105716.	-159328.	-509288.	-1280800.	-915476.	-1447648.	-602360.	869396.	1259680.
CUMULATIVE CASH FLOW	-74360.	-180076.	-339404.	-848692.	-2129492.	-3044968.	-4492616.	-5094976.	-4225580.	-2965900.
RETURN ON INVESTMENT(PCT)	.00	.00	.00	.00	-89.75	-39.52	-37.13	20.47	48.31	48.37
NET INCOME TO SALES (PCT)	.00	.00	.00	.00	.00	.00	.00	10.68	17.60	19.44
OPERATING EXPENSE										
UNIT MANUFACTURING COST	.00	.00	.00	.00	.00	.00	.00	6.00	6.00	6.00
UNITS MANUFACTURED(UNITS)	0.	0.	0.	0.	0.	0.	0.	480000.	960000.	1200000.
COST OF GOODS MFG.	0.	0.	0.	0.	0.	0.	0.	2880000.	5760000.	7200000.
AVERAGE INVENTORY***	0.	0.	0.	0.	0.	0.	0.	576000.	1152000.	1440000.
R AND D EXPENSE	130000.	173000.	251000.	840000.	796000.	343000.	571000.	428000.	287000.	0.
ENGINEERING EXPENSE	0.	0.	0.	0.	0.	0.	0.	144000.	288000.	360000.
SELLING EXPENSE	0.	0.	0.	0.	0.	0.	0.	300000.	600000.	750000.
ADMINISTRATION EXPENSES	0.	0.	0.	0.	0.	0.	0.	288000.	576000.	720000.
DEPRECIATION EXPENSES**	0.	0.	0.	0.	75000.	135000.	233000.	233000.	233000.	361000.
TOTAL OPERATING EXPENSES	130000.	173000.	251000.	840000.	871000.	478000.	804000.	4273000.	7744000.	9391000.
INVESTMENT										
RECEIVABLES (AVG)	0.	0.	0.	0.	0.	0.	0.	1200000.	2400000.	3000000.
INVENTORIES (AVG)	0.	0.	0.	0.	0.	0.	0.	576000.	1152000.	1440000.
ANNUAL PLANT AND EQUIP.	0.	0.	0.	0.	750000.	600000.	980000.	0.	0.	1280000.
CUMULATIVE PLANT + EQUIP.	0.	0.	0.	0.	750000.	1350000.	2330000.	2330000.	2330000.	3610000.
ANNUAL DEPRECIATION	0.	0.	0.	0.	75000.	135000.	233000.	233000.	233000.	361000.
CUMULATIVE DEPRECIATION	0.	0.	0.	0.	75000.	210000.	443000.	676000.	909000.	1270000.
NET PLANT + EQUIP.	0.	0.	0.	0.	675000.	1140000.	1887000.	1654000.	1421000.	2340000.
OTHER INVESTMENT****	0.	0.	0.	0.	0.	0.	0.	300000.	600000.	750000.
NET ANNUAL INVESTMENT	0.	0.	0.	0.	675000.	1140000.	1887000.	3130000.	4373000.	6030000.
PRESENT VALUE OF ANNUAL CASH FLOW		10754509.								

* ASSUME TAX LOSS IS CREDITED AGAINST OTHER BUSINESS INCOME.
** THIS ITEM IS NORMALLY INCLUDED IN VARIOUS OVERHEAD ACCOUNTS.
*** INVENTORY DERIVATION IS HIGHLY SIMPLIFIED, BUT APPROXIMATES MORE COMPLEX METHODS
**** INCLUDES MISC. LIABILITIES SUCH AS ACCOUNTS PAYABLE, RESERVES, SUNDRY CREDITOR ITEMS

Figure IV-2A. Isoenzymes Cash Flow Analysis – Case A

8/6/75 CASE:

	85	86	87	88	89	90	91	92	93	94
TOTAL MARKET (UNITS)	20000000.	25000000.	30000000.	35000000.	40000000.	45000000.	50000000.	50000000.	0.	0.
MARKET SHARE (PCT)	6.00	6.00	6.70	7.10	7.50	7.80	8.00	10.00	.00	.00
UNITS SOLD (UNITS)	1200000.	1500000.	2010000.	2485000.	3000000.	3510000.	4000000.	5000000.	0.	0.
UNIT PRICE	15.	15.	14.	13.	10.	9.	8.	6.	0.	0.
SALES	18000000.	22500000.	28140000.	32305000.	30000000.	31590000.	32000000.	32500000.	0.	0.
OPERATING EXPENSES	10122800.	12592000.	16604140.	20434540.	20749000.	21513700.	18621000.	19336000.	0.	0.
GROSS PROFITS	7877200.	9908000.	11535860.	11870460.	9251000.	10076300.	13379000.	13164000.	0.	0.
ANNUAL INVESTMENT	6970400.	8031000.	9029720.	11094670.	10709000.	10518100.	9629000.	9363000.	0.	0.
CUMULATIVE GROSS PROFITS	15922200.	25830200.	37366060.	49236520.	58487520.	68563820.	81942820.	95106820.	0.	0.
BASE FOR INTEREST EXP.	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
INTEREST EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
INCOME BEFORE TAXES	7877200.	9908000.	11535860.	11870460.	9251000.	10076300.	13379000.	13164000.	0.	0.
TAXES	3781056.	4755840.	5537213.	5697821.	4440480.	4836624.	6421920.	6318720.	0.	0.
NET INCOME AFTER TAXES	4096144.	5152160.	5998647.	6172639.	4810520.	5239676.	6957080.	6845280.	0.	0.
NET CHANGE IN INVEST.	940400.	1060600.	998720.	2064950.	-385670.	-190900.	-889100.	-266000.	0.	0.
ANNUAL CASH FLOW	3155744.	4091560.	4999927.	4107689.	5196190.	5430576.	7846180.	7111280.	0.	0.
CUMULATIVE CASH FLOW	189844.	4281404.	9281331.	13389020.	18585210.	24015786.	31861966.	38973246.	0.	0.
RETURN ON INVESTMENT(PCT)	58.76	64.15	66.43	55.64	44.92	49.82	72.25	73.11	.00	.00
NET INCOME TO SALES (PCT)	22.76	22.90	21.32	19.11	16.04	16.59	21.74	21.06	.00	.00
O P E R A T I N G E X P E N S E										
UNIT MANUFACTURING COST	5.30	5.30	5.30	5.30	4.50	4.00	3.00	2.50	.00	.00
UNITS MANUFACTURED(UNITS)	1440000.	1800000.	2412000.	2982000.	3600000.	4212000.	4800000.	6000000.	0.	0.
COST OF GOODS MFG.	7632000.	9540000.	12783600.	15804600.	16200000.	16848000.	14400000.	15000000.	0.	0.
AVERAGE INVENTORY***	1526400.	1908000.	2556720.	3160920.	3240000.	3369600.	2880000.	3000000.	0.	0.
R AND D EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
ENGINEERING EXPENSE	381600.	477000.	639180.	790230.	810000.	842400.	720000.	750000.	0.	0.
SELLING EXPENSE	900000.	1125000.	1407000.	1615250.	1500000.	1579500.	1600000.	1625000.	0.	0.
ADMINISTRATION EXPENSES	763200.	954000.	1278360.	1580460.	1620000.	1684800.	1440000.	1500000.	0.	0.
DEPRECIATION EXPENSES**	446000.	496000.	496000.	644000.	619000.	559000.	461000.	461000.	0.	0.
TOTAL OPERATING EXPENSES	10122800.	12592000.	16604140.	20434540.	20749000.	21513700.	18621000.	19336000.	0.	0.
I N V E S T M E N T										
RECEIVABLES (AVG)	3600000.	4500000.	5628000.	6461000.	6000000.	6318000.	6400000.	6500000.	0.	0.
INVENTORIES (AVG)	1526400.	1908000.	2556720.	3160920.	3240000.	3369600.	2880000.	3000000.	0.	0.
ANNUAL PLANT AND EQUIP.	850000.	500000.	0.	1480000.	500000.	0.	0.	0.	0.	0.
CUMULATIVE PLANT + EQUIP.	4460000.	4960000.	4960000.	6440000.	6940000.	6940000.	6940000.	6940000.	0.	0.
ANNUAL DEPRECIATION	446000.	496000.	496000.	644000.	619000.	559000.	461000.	461000.	0.	0.
CUMULATIVE DEPRECIATION	1716000.	2212000.	2708000.	3352000.	3971000.	4530000.	4991000.	5452000.	0.	0.
NET PLANT + EQUIP.	2744000.	2748000.	2252000.	3088000.	2969000.	2410000.	1949000.	1488000.	0.	0.
OTHER INVESTMENT****	300000.	1125000.	1407000.	1615250.	1500000.	1579500.	1600000.	1625000.	0.	0.
NET ANNUAL INVESTMENT	6970400.	8031000.	9029720.	11094670.	10709000.	10518100.	9629000.	9363000.	0.	0.
PRESENT VALUE OF ANNUAL CASH FLOW			10754509.							

* ASSUME TAX LOSS IS CREDITED AGAINST OTHER BUSINESS INCOME.
** THIS ITEM IS NORMALLY INCLUDED IN VARIOUS OVERHEAD ACCOUNTS.
*** INVENTORY DERIVATION IS HIGHLY SIMPLIFIED, BUT APPROXIMATES MORE COMPLEX METHODS
**** INCLUDES MISC. LIABILITIES SUCH AS ACCOUNTS PAYABLE, RESERVES, SUNDRY CREDITOR ITEMS

Figure IV-2B. Isoenzymes Cash Flow Analysis - Case A

8/6/75

INPUTS:	75	76	77	78	79	80	81	82	83	84
TOTAL MARKET (UNITS)	0.	0.	0.	0.	0.	20000000.	20000000.	20000000.	20000000.	20000000.
MARKET SHARE (PCT)	0.	0.	0.	0.	0.	0.	0.	2.	4.	5.
UNIT PRICE	0.	0.	0.	0.	0.	0.	0.	15.	15.	15.
UNIT MANUFACTURING COST	.00	.00	.00	.00	.00	.00	.00	6.00	6.00	6.00
R AND D EXPENSE	0.	0.	0.	0.	0.	66000.	571000.	428000.	288000.	0.
ANNUAL PLANT AND EQUIP.	0.	0.	0.	0.	750000.	600000.	980000.	0.	0.	1280000.

INPUTS:	85	86	87	88	89	90	91	92	93	94
TOTAL MARKET (UNITS)	20000000.	25000000.	30000000.	35000000.	40000000.	45000000.	50000000.	50000000.	0.	0.
MARKET SHARE (PCT)	6.	6.	7.	7.	8.	8.	8.	10.	0.	0.
UNIT PRICE	15.	15.	14.	13.	10.	9.	8.	6.	0.	0.
UNIT MANUFACTURING COST	5.30	5.30	5.30	5.30	4.50	4.00	3.00	2.50	.00	.00
R AND D EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
ANNUAL PLANT AND EQUIP.	850000.	500000.	0.	1480000.	500000.	0.	0.	0.	0.	0.

PARAMETRIC PERCENTAGES:

PARAMETER	IDENTIFIER	VALUE	PARAMETER	IDENTIFIER	VALUE
INTEREST RATE	P11	10.00	UNITS MANUFACTURED PCT.	P21	120.00
AVERAGE INVENTORY PCT.	P23	20.00	ENGINEERING EXPENSE PCT.	P26	5.00
SELLING EXPENSE PCT.	P27	5.00	ADMINISTRATION EXPENSE PCT	P28	10.00
RECEIVABLES PCT.	P31	20.00	DEPRECIATION PERIOD(YRS)	P35	10.00
OTHER INVESTMENT PCT.	P38	5.00			

PERCENTAGE OF BASELINE USED INPUTS	IDENTIFIER	PCT	ADD/SUB FROM BASELINE INPUTS IDENTIFIER	VALUE
TOTAL MARKET	X1	100	A1	0.
MARKET SHARE	X2	100	A2	0.
UNIT PRICE	X3	100	A3	.00
UNIT MANUFACTURING COST	X4	100	A4	0.
R AND D EXPENSE	X5	100	A5	0.
ANNUAL PLANT AND EQUIP.	X6	100	A6	0.

Figure IV-3. Isoenzymes Input Values - Case B

8/6/75

	75	76	77	78	79	80	81	82	83	84
TOTAL MARKET (UNITS)	0.	0.	0.	0.	0.	20000000.	20000000.	20000000.	20000000.	20000000.
MARKET SHARE (PCT)	.00	.00	.00	.00	.00	.00	.00	2.00	4.00	5.00
UNITS SOLD (UNITS)	0.	0.	0.	0.	0.	0.	0.	400000.	800000.	1000000.
UNIT PRICE	0.	0.	0.	0.	0.	0.	0.	15.	15.	15.
SALES	0.	0.	0.	0.	0.	0.	0.	6000000.	12000000.	15000000.
OPERATING EXPENSES	0.	0.	0.	0.	75000.	201000.	804000.	4273000.	7745000.	9391000.
GROSS PROFITS	0.	0.	0.	0.	-75000.	-201000.	-804000.	1727000.	4255000.	5609000.
ANNUAL INVESTMENT	0.	0.	0.	0.	675000.	1140000.	1887000.	3130000.	4373000.	6030000.
CUMULATIVE GROSS PROFITS	0.	0.	0.	0.	-75000.	-276000.	-1080000.	647000.	4902000.	10511000.
BASE FOR INTEREST EXP.	0.	0.	0.	0.	750000.	1416000.	2967000.	2483000.	0.	0.
INTEREST EXPENSE	0.	0.	0.	0.	75000.	141600.	296700.	248300.	0.	0.
INCOME BEFORE TAXES	0.	0.	0.	0.	-150000.	-342600.	-1100700.	1478700.	4255000.	5609000.
TAXES	0.	0.	0.	0.	-72000.	-164448.	-528336.	709776.	2042400.	2692320.
NET INCOME AFTER TAXES	0.	0.	0.	0.	-78000.	-178152.	-572364.	768924.	2212600.	2916680.
NET CHANGE IN INVEST.	0.	0.	0.	0.	675000.	465000.	747000.	1243000.	1243000.	1657000.
ANNUAL CASH FLOW	0.	0.	0.	0.	-753000.	-643152.	-1319364.	-474076.	969600.	1259680.
CUMULATIVE CASH FLOW	0.	0.	0.	0.	-753000.	-1396152.	-2715516.	-3189592.	-2219992.	-960312.
RETURN ON INVESTMENT(PCT)	.00	.00	.00	.00	-11.56	-15.63	-30.33	24.57	50.60	48.37
NET INCOME TO SALES (PCT)	.00	.00	.00	.00	.00	.00	.00	12.82	18.44	19.44
OPERATING EXPENSE										
UNIT MANUFACTURING COST	.00	.00	.00	.00	.00	.00	.00	6.00	6.00	6.00
UNITS MANUFACTURED(UNITS)	0.	0.	0.	0.	0.	0.	0.	480000.	960000.	1200000.
COST OF GOODS MFG.	0.	0.	0.	0.	0.	0.	0.	2880000.	5760000.	7200000.
AVERAGE INVENTORY***	0.	0.	0.	0.	0.	0.	0.	576000.	1152000.	1440000.
R AND D EXPENSE	0.	0.	0.	0.	0.	66000.	571000.	428000.	288000.	0.
ENGINEERING EXPENSE	0.	0.	0.	0.	0.	0.	0.	144000.	288000.	360000.
SELLING EXPENSE	0.	0.	0.	0.	0.	0.	0.	300000.	600000.	750000.
ADMINISTRATION EXPENSES	0.	0.	0.	0.	0.	0.	0.	288000.	576000.	720000.
DEPRECIATION EXPENSES**	0.	0.	0.	0.	75000.	135000.	233000.	233000.	233000.	361000.
TOTAL OPERATING EXPENSES	0.	0.	0.	0.	75000.	201000.	804000.	4273000.	7745000.	9391000.
INVESTMENT										
RECEIVABLES (AVG)	0.	0.	0.	0.	0.	0.	0.	1200000.	2400000.	3000000.
INVENTORIES (AVG)	0.	0.	0.	0.	0.	0.	0.	576000.	1152000.	1440000.
ANNUAL PLANT AND EQUIP.	0.	0.	0.	0.	750000.	600000.	980000.	0.	0.	1260000.
CUMULATIVE PLANT + EQUIP.	0.	0.	0.	0.	750000.	1350000.	2330000.	2330000.	2330000.	3610000.
ANNUAL DEPRECIATION	0.	0.	0.	0.	75000.	135000.	233000.	233000.	233000.	361000.
CUMULATIVE DEPRECIATION	0.	0.	0.	0.	75000.	210000.	443000.	676000.	909000.	1270000.
NET PLANT + EQUIP.	0.	0.	0.	0.	675000.	1140000.	1887000.	1654000.	1421000.	2340000.
OTHER INVESTMENT****	0.	0.	0.	0.	0.	0.	0.	300000.	600000.	750000.
NET ANNUAL INVESTMENT	0.	0.	0.	0.	675000.	1140000.	1887000.	3130000.	4373000.	6030000.
PRESENT VALUE OF ANNUAL CASH FLOW		12153861.								

* ASSUME TAX LOSS IS CREDITED AGAINST OTHER BUSINESS INCOME.
** THIS ITEM IS NORMALLY INCLUDED IN VARIOUS OVERHEAD ACCOUNTS.
*** INVENTORY DERIVATION IS HIGHLY SIMPLIFIED, BUT APPROXIMATES MORE COMPLEX METHODS
**** INCLUDES MISC. LIABILITIES SUCH AS ACCOUNTS PAYABLE, RESERVES, SUNDRY CREDITOR ITEMS

Figure IV-4A. Isoenzymes Cash Flow Analysis - Case B

8/6/75 CASE:

	85	86	87	88	89	90	91	92	93	94
TOTAL MARKET (UNITS)	20000000.	25000000.	30000000.	35000000.	40000000.	45000000.	50000000.	50000000.	0.	0.
MARKET SHARE (PCT)	6.00	6.00	6.70	7.10	7.50	7.80	8.00	10.00	.00	.00
UNITS SOLD (UNITS)	1200000.	1500000.	2010000.	2485000.	3000000.	3510000.	4000000.	5000000.	0.	0.
UNIT PRICE	15.	15.	14.	13.	10.	9.	8.	6.	0.	0.
SALES	18000000.	22500000.	28140000.	32305000.	30000000.	31590000.	32000000.	32500000.	0.	0.
OPERATING EXPENSES	10122800.	12592000.	16604140.	20434540.	20749000.	21513700.	18621000.	19336000.	0.	0.
GROSS PROFITS	7877200.	9908000.	11535860.	11870460.	9251000.	10076300.	13379000.	13164000.	0.	0.
ANNUAL INVESTMENT	6970400.	8031000.	9029720.	11094670.	10709000.	10518100.	9629000.	9363000.	0.	0.
CUMULATIVE GROSS PROFITS	18386200.	28294200.	39830060.	51700520.	60953520.	71029820.	84408820.	97572820.	0.	0.
BASE FOR INTEREST EXP.	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
INTEREST EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
INCOME BEFORE TAXES	7877200.	9908000.	11535860.	11870460.	9251000.	10076300.	13379000.	13164000.	0.	0.
TAXES	3781056.	4755840.	5537213.	5697821.	4440480.	4836624.	6421920.	6318720.	0.	0.
NET INCOME AFTER TAXES	4096144.	5152160.	5998647.	6172639.	4810520.	5239676.	6957080.	6845280.	0.	0.
NET CHANGE IN INVEST.	940400.	1060600.	998720.	2064950.	-385670.	-190900.	-889100.	-266000.	0.	0.
ANNUAL CASH FLOW	3155744.	4091560.	4999927.	4107689.	5196190.	5430576.	7846180.	7111280.	0.	0.
CUMULATIVE CASH FLOW	2195432.	6286992.	11286919.	15394608.	20590798.	26021374.	33867554.	40978834.	0.	0.
RETURN ON INVESTMENT(PCT)	58.76	64.15	66.43	55.64	44.92	49.82	72.25	73.11	.00	.00
NET INCOME TO SALES (PCT)	22.76	22.90	21.32	19.11	16.04	16.59	21.74	21.06	.00	.00
OPERATING EXPENSE										
UNIT MANUFACTURING COST	5.30	5.30	5.30	5.30	4.50	4.00	3.00	2.50	.00	.00
UNITS MANUFACTURED(UNITS)	1440000.	1800000.	2412000.	2982000.	3600000.	4212000.	4800000.	6000000.	0.	0.
COST OF GOODS MFG.	7632000.	9540000.	12783600.	15804600.	16200000.	16848000.	14400000.	15000000.	0.	0.
AVERAGE INVENTORY***	1526400.	1908000.	2556720.	3160920.	3240000.	3369600.	2880000.	3000000.	0.	0.
R AND D EXPENSE	0.	0.	0.	0.	0.	0.	0.	0.	0.	0.
ENGINEERING EXPENSE	381600.	477000.	639180.	790230.	810000.	842400.	720000.	750000.	0.	0.
SELLING EXPENSE	900000.	1125000.	1407000.	1615250.	1500000.	1579500.	1600000.	1625000.	0.	0.
ADMINISTRATION EXPENSES	763200.	954000.	1278360.	1580460.	1620000.	1684800.	1440000.	1500000.	0.	0.
DEPRECIATION EXPENSES**	446000.	496000.	496000.	644000.	619000.	559000.	461000.	461000.	0.	0.
TOTAL OPERATING EXPENSES	10122800.	12592000.	16604140.	20434540.	20749000.	21513700.	18621000.	19336000.	0.	0.
INVESTMENT										
RECEIVABLES (AVG)	3600000.	4500000.	5628000.	6461000.	6000000.	6318000.	6400000.	6500000.	0.	0.
INVENTORIES (AVG)	1526400.	1908000.	2556720.	3160920.	3240000.	3369600.	2880000.	3000000.	0.	0.
ANNUAL PLANT AND EQUIP.	250000.	500000.	0.	1480000.	500000.	0.	0.	0.	0.	0.
CUMULATIVE PLANT + EQUIP.	4460000.	4960000.	4960000.	6440000.	6940000.	6940000.	6940000.	6940000.	0.	0.
ANNUAL DEPRECIATION	446000.	496000.	496000.	644000.	619000.	559000.	461000.	461000.	0.	0.
CUMULATIVE DEPRECIATION	1716000.	2212000.	2708000.	3352000.	3971000.	4530000.	4991000.	5452000.	0.	0.
NET PLANT + EQUIP.	2744000.	2748000.	2252000.	3088000.	2969000.	2410000.	1949000.	1488000.	0.	0.
OTHER INVESTMENT****	900000.	1125000.	1407000.	1615250.	1500000.	1579500.	1600000.	1625000.	0.	0.
NET ANNUAL INVESTMENT	6970400.	8031000.	9029720.	11094670.	10709000.	10518100.	9629000.	9363000.	0.	0.
PRESENT VALUE OF ANNUAL CASH FLOW			12158861.							

* ASSUME TAX LOSS IS CREDITED AGAINST OTHER BUSINESS INCOME.
** THIS ITEM IS NORMALLY INCLUDED IN VARIOUS OVERHEAD ACCOUNTS.
*** INVENTORY DERIVATION IS HIGHLY SIMPLIFIED, BUT APPROXIMATES MORE COMPLEX METHODS
**** INCLUDES MISC. LIABILITIES SUCH AS ACCOUNTS PAYABLE, RESERVES, SUNDRY CREDITOR ITEMS

Figure IV-4B. Isoenzymes Cash Flow Analysis - Case B

The further analysis of the concept and of these areas for increasing or decreasing conservatism are beyond the scope of this study. However, the possibilities are presently very encouraging and early ground lab studies of the process phenomenology are highly recommended.

Figure IV-5 presents a plot of the key financial measures for the Isoenzyme product.

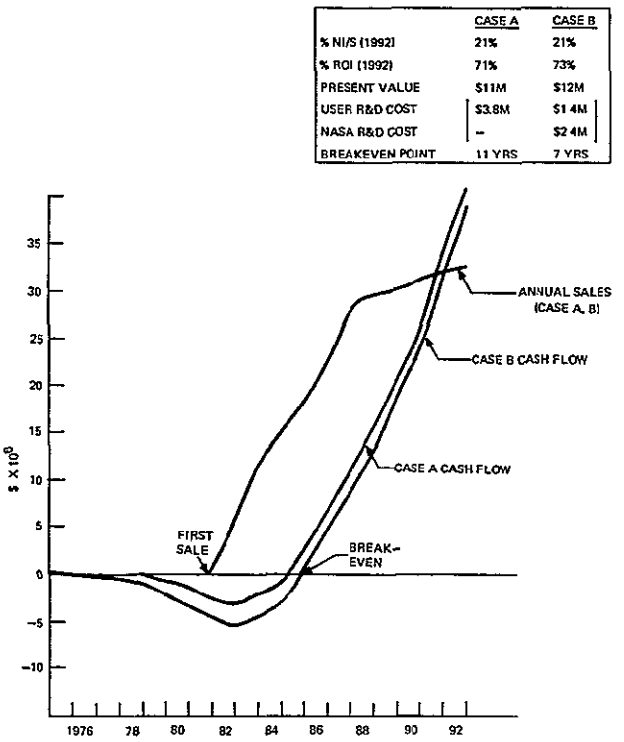

Figure IV-5. Isoenzymes Cash Flow

SECTION V
MARKET ANALYSIS

V.1 INTRODUCTION

The market addressed is that for diagnostic kits sold to physicians and clinics, for use in diagnosis of up to 10 diseases, none of which can be given early or accurate diagnosis with presently available methods. The period of interest is 1980-1992. The specific diseases and kit antibodies are undefined (creatine kinase and glycogen phosphorylase are candidates) and are to be selected during the development program which extends from 1975-1982. The space product, which makes the diagnostic kit feasible, is a set of up to 10 antigens which are obtained via gel electrophoresis on a preparative scale (in the concept used, one 5 cm diameter x 220 cm length gel tube provides 0.1 gram of purified antigenic protein which is specific for one disease state).

While disease treatment may be a future capability, the market forecast is limited for the present, to demand for diagnostic purposes only.

Virtually no precedent exists for forecasting of kit demand and kit price, and so the forecasts given here must be used with caution.

A conceptual description of the business which would address the market of interest is given in the following paragraphs.

V.1.1 ORGANIZATION

The Business is established as a product line under a product manager in the house of an existing manufacturer of biologicals. An on-going association has been formed by the manufacturer with one or more hospitals and clinics for the testing, certification, and introduction of space-processed isoenzyme products. The roughly one to five million diagnostic kits produced per year are marketed via an expansion of the existing sales and distribution channels of the manufacturer.

V.1.2 FACILITIES AND EQUIPMENT

New facilities, associated with the existing plant, have been prepared for preparation of gel tubes, quality control, and flight preparation of the space isoenzyme separation facilities. Equipment for gel preparation, tube loading, space facility loading, etc. has been installed, mostly of conventional design. Gel preparation facility capacity is in the order of 1 to 4 hundred large (5-8 cm diameter) tubes per year.

Space processing facilities (2 or more units) are maintained for in-space electrophoretic separation of isoenzymes, using Shuttle transport and in-orbit services.

The isoenzyme/antibody preparation facility is equipped with conventional gel tube handling, gel removal, slicing, etc. equipment for preparation of animal injections of the antigen. An animal farm, probably a horse farm of 100 or more horses is maintained for growth of antibodies. Periodic blood drawings from the animals are processed at a facility which is equipped with conventional equipment for preparation of gamma globulin fractions and preparation of the diagnostic kits which constitute the finished product.

V.1.3 INITIAL R&D

To reach production status, the Business has incurred a significant expense in research of candidate isoenzymes, gel preparation and electrophoresis techniques, and facility development, both ground and in-space, to reach full scale production capability. This investment is taken as $1.4 million, (Case B), spread over 4 years after government-funded demonstration of process feasibility. In association with hospitals and clinics, the Business has conducted an extensive test program using experimental products to establish the marketability and high level (90-95%) effectiveness of the diagnostic kits in diagnosis of diseases.

V.1.4 CONTINUING R&D

The Business maintains a continuing engineering (product and process development) program of 5% of sales to assure a competitive selection of isoenzyme products.

V.1.5 SPACE SHUTTLE SERVICES

Arrangements have been made with NASA for regular (say monthly) shuttle services, including up-transport, on-orbit operations in low earth orbit, and down-transport services. On-orbit operating times are 7 days or more per flight. The procedures for using shuttle services will have been established during the R&D phase, and service charges, legal considerations, schedules, etc. will have been agreed to and documented.

V.1.6 INVENTORY AND RECEIVABLES

The Business operates at a relatively even month-to-month production level. Inventory is maintained on an annual basis of 20% of sales, and Receivables average 20% of sales.

V.2 PRODUCT BENEFITS

The benefits of the new antigen/diagnostic kit are the early and accurate diagnosis of disease states. A low kit price would allow screening of general populations in addition to the specific diagnosis of suspected cases. Early diagnosis would mean more time for specific treatment and a higher patient recovery rate. Accurate diagnosis (virtually no false positives and no false negatives) would allow avoidance of unnecessary treatment, concentration on specific curative treatments, and an intangible benefit in the form of patient peace-of-mind. A long range benefit (not pursued in this market analysis) is that of specific disease treatment of diseases which presently lack effective curative methods.

V.3 COMPETITIVE PRODUCTS AND COMPETITORS

The only present competitive products are those antigenic proteins which are available for just a few diseases. These products are relatively impure, thus lacking specificity

and giving an undesirable number of false positive diagnoses. When available, the space-processed product will most likely have no competitor with the equivalent specificity.

V.4 POTENTIAL ALTERNATIVES

No presently identifiable alternatives exist for the diagnostic capability proposed. No ground-based equivalent exist for the isolation of purified isoenzymes. Although much work is being done in this area, there is no reason to expect the development of a ground-based process which will accomplish what the space process may achieve by virtue of zero-G operations.

V.5 MARKET FORECASTING

The market has been forecast on the basis of low-priced kits being made available, and that selective screening followed by widespread screening in the U.S. only is conducted under government or other auspices. Assume a U.S. population of interest of 200 Million persons, and 10 relatively high incidence diseases, each of which has an incidence rate of 1%. The incidence for these 10 diseases is then (10 x 0.01 x 200,000,000) or 20,000,000 cases. If the discovery rate is one diseased patient in every 5 examined, 100 million diagnoses would be required to identify all diseased patients. Assuming a 5-year selective screening program, a demand for 20 million kits per year is obtained, for the U.S. only. A subsequent general screening program for the total population yields a demand for 50 million kits per year. (20,000,000 cases, discovery rate one in twenty, 8 year program). Recognizing a gradual building, demand would increase from 20 million kits in 1985 to 50 million by 1992.

Extrapolation of this basis to the world demand would, of course, generate huge numbers. In summary, a demand of 20-50 million diagnostic kits for the total demand 1980-1992 appears conservative, and is presented as follows.

Year	Kits (millions)	Year	Kits (millions)
1980	20	1986	25
1981	20	1987	30
1982	20	1988	35
1983	20	1989	40
1984	20	1990	45
1985	20	1991	50
		1992	50

Figure V-1. Demand for Diagnostic Kits, 1980-1992

V.6 PRODUCT QUANTITIES AND PRICING

The forecast of market share in terms of units sold is based on successful isolation of at least several of the 10 desired isoenzymes and successful satisfaction of about 8% of the demand given in paragraph IV. 5 by 1991, giving a sales forecast as follows.

Year	Sales (kits)	Year	Sales (kits)
1980	-	1986	1500K
1981	-	1987	2000K
1982	400K	1988	2500K
1983	800K	1989	3000K
1984	1000K	1990	3500K
1985	1200K	1991	4000K
		1992	5000K

Figure V-2. Sales Forecast (Diagnostic Kits) 1980-1992

A price per kit of $15 is estimated for the 1980-1985 period, with a drop to $6 per kit by about 1992 as part of the market expansion to include general population screening.

V.7 PRODUCT LIFE CYCLE

The introduction and growth phases of the product life cycle will probably be production limited, as well as being paced by the degree of success in working with physicians and clinics to establish confidence. Product decline and exit would be attributable to the arrival of a much cheaper (e.g., ground processed) alternate diagnostic tool.

However, addition of new isoenzymes to the product line could easily extend the product life cycle beyond that shown below.

Phase	From (year)	To (year)
Introduction	1980	1983
Growth	1984	1991
Maturity	1991	1999
Decline	1999	2009
Exit	2009	2019

Figure V-3. Isoenzyme Diagnostic Kit Product Life Cycle

SECTION VI

COST/VALUE FOR PRODUCTION

VI. 0 ISOENZYME PROCESSING

This section presents the baseline production concept for producing isoenzyme diagnostic kits, along with the assumptions and key findings for the product venture. It must be remembered that all figures given here are conceptual only, and are subject to change upon further and more detailed investigation.

VI. 1 FLIGHTS AND RESOURCES REQUIRED FOR PILOT PLANT AND FULL SCALE PRODUCTION

The isoenzyme production process presents a sequence of ground-space-ground process steps with one in-space process step required, that of zero-g electrophoretic separation. A throughput analysis, unit product cost breakdown, and rough breakdowns of associated costs are provided in the following paragraphs.

VI. 1. 1 ANALYSIS OF PRODUCT VOLUME AND TIME VS. PAYLOAD CAPACITY AND TIME

The forecasted manufacturing volume is an initial output of 400, 000 kits in 1982, building up to a level of 5 million kits per year in 1992. The 1982 start implies the start of small scale production while the R&D program (which ends in 1983) is still in process. The small quantities of space-processed product required for 400, 000 units of output makes this a reasonable possibility. The electrophoretic separator envisioned would process 600 milligrams of protein per 7-day flight, which equates to about 120, 000 diagnostic kits. Thus, in the first year of production, about 3-4 flights of one separator would suffice, or a single 7-day flight with 4 separators would accomplish the same purpose. At full scale production of 5 million kits per year, 10 flights per year with 4 or 5 separators aboard would be sufficient. The electrophoretic separator would be a relatively compact, modular unit, so that flights of multiple separators would appear to be straightforward. Another possibility would be

to scale up the baseline separator for larger throughput (larger tubes or plates), so that no payload capacity problem appears likely. A throughput analysis for the space process and ground process steps is shown in Figure VI-1, for an annual throughput of 1.2 million units.

VI.1.2 ANALYSIS OF PROCESSING SUPPORT REQUIREMENTS VS. SHUTTLE/ SPACELAB AVAILABLE RESOURCES

The electrophoretic separator is conceived as being self-contained in terms of gel tube storage, and buffer and coolant supplies, so that the only support requirements would be for input power and crew attention. The separator would operate on a nominally 24-hour cycle, with say, 6 tube separation cycles per 7-day flight. Operator duties would be to install the gel tube, (taken from freezer storage) initialize the process controls, and monitor the process by periodic observation of a meter or fault indicators. An average of one man hour per day of crew support is estimated. A single separator power requirement is roughly estimated at 300 watts continuous, so that at a production level of 5 million kits per year, and assuming 10 flights per year, the power requirement per flight would be, say, 5 x 300 watts = 1500 watts continuous, or an energy requirement of 1500 watts x 156 hours = 234 KWH.

VI.1.3 DETERMINATION OF NUMBER OF FLIGHTS FOR PILOT PLANT AND PRODUCTION

A baseline assumption of 10 flights per year has been used, relative to an annual throughput of 1.2 million kits. Increase of production to 5 million kits per year would be accommodated by increasing the number of separator stations on each flight. At present, no basis exists for assessing the production level required relative to customer needs (e.g., seasonal demand, storage limitations, number of different types of diagnostic kits required over a typical year, etc.) Thus an essentially linear output has been assumed. It is conceivable that a very few flights of very high output would be more economical, or necessary to meet customer orders. It is also possible that a high priority order could call for a special unscheduled

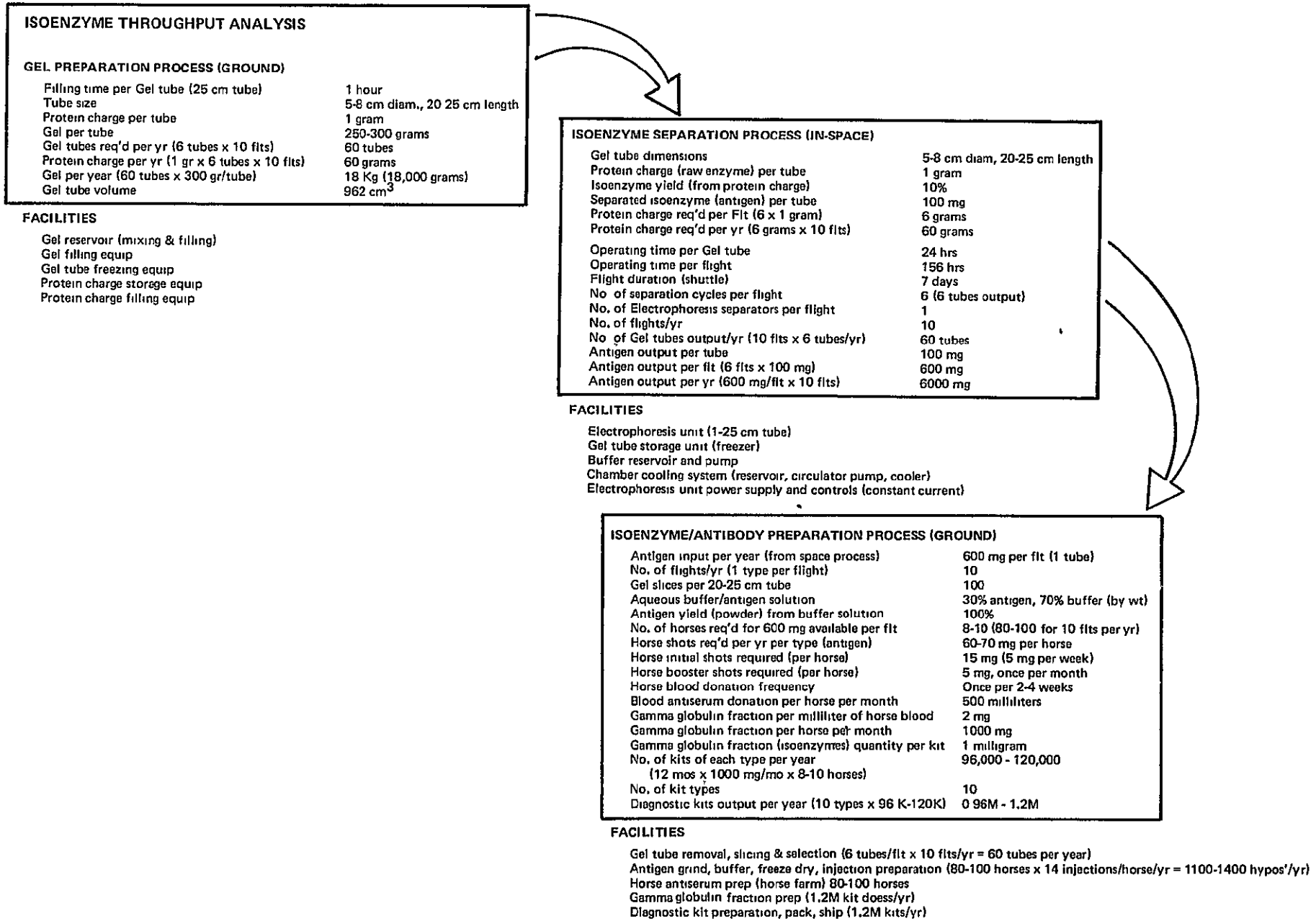

Figure VI-1. Isoenzyme Space Product Throughput Analysis

flight. In the meantime, the best basis appears to be to use the 10 flights per year (one to 5 flights per year for initial production) and to assume that the flexibility in size or number of separators can be used to accommodate any flight frequency restrictions.

VI.1.4 DETERMINATION OF RESOURCES REQUIRED FOR PILOT PLANT AND PRODUCTION

A summary of the production resource requirements is shown in Figure VI-2. Plant and equipment requirements are roughly estimated as shown in Figure VI-3. The The horse farm requirements are shown separately in Figure VI-4. Roughly, about 100 overhead and 400 manufacturing personnel might be required, in full scale production (Figure VI-5).

VI.2 ANALYSIS OF PRODUCTION COSTS

A breakdown of the manufacturing costs by process step for an annual production of 1.2 million units is shown in Figures VI-6, VI-7, and VI-8. The unit cost of $2.49 is roughly the same as used for the year 1992 in the financial forecast ($2.50). A figure of $6.00 was used as unit cost in the early years when the selling price was high.

VI.2.1 SHUTTLE/SPACELAB OPERATION COSTS AND RESOURCE COSTS

Space operations costs at an annual production level of 1.2 million units are estimated at $1292K (Figure VI-6). Most of this amount is for shuttle service charges as calculated in Figure VI-8. Linear extrapolation of these service charges to a production level of 5 million units per year (1992) would give an annual space service charge of about $5 million, against annual sales of about $33 million.

VI.2.2. DEFINITION OF ADDITIONAL NON-SPACE PROGRAM COSTS

The post-space process steps, for antibody growth, antibody processing and kit preparation, account for about 40% of the unit manufacturing cost (Figure VI-6).

MATERIALS

- Gel tubes, gels, proteins, buffers, tissue, sera, diagnostic kit materials,

SERVICES

Shuttle launch and support (NASA)

Product test (hospitals, clinics)

EQUIPMENT

Preparative scale electrophoresis equipment (0-G)

Gel tube preparation equipment

Antibody preparation equipment

Diagnostic kit preparation equipment

FACILITIES

Gel tube preparation Lab (production)

Antigen preparation Lab (production)

Launch and Return Facilities (Shuttle) (NASA)

Antibody Growth Facility (Horse Farm)

Diagnostic Kit preparation facility (production)

Product Quality Control Lab

SPECIAL MANPOWER SKILLS

Biochemists and technicians

Product test and evaluation clinicians

Figure VI-2. Isoenzymes Production Resource Requirements Summary

		1.2M kits/yr.	5M kits/yr.
Gel Prep. facility			
50 x 50 ft. = 2,500 sq. ft.			
@ $100/sq. ft.	=	250K	
+ Equip.		100K	
		350K	x 3 = 1,050K
Space Proc'g. Equip.			
2 facil @ $500K	=	1,000K	x 3 = 3,000K
Horse Farm incl. Equip.		400K	x 3 = 1,200K
Antibody Prep. Facility (Lease & improvement of existing facility)			
10 kits/hr./oper. x 2,080 =			
20,800 kits/yr./oper.			
1.2M - 20,800 = 58 operators			
@ 50 sq. ft./oper. = 2,900 sq. ft.			
x 2 = 5,800 sq. ft. @ $100/sq. ft.	=	580K	x 3 = 1,740K
Total		2,330K	6,990K

Time Scale:	78	79	80	81	82	83	84	85	86	87	88	89	90	
Gel Preparation		250	100	-	-	-	300	350	-	-	-	-	-	
Space Facility		500	500					500	500		500	500		
Horse Farm				400			400				400			
Antibody Prep				580			580				580			
Total ($K)	-	750	600	980	-	-	1280	850	500	-	1480	500	-	-
Cum	-	750	1350	2330	2330	2330	3610	4460	4960	4960	6440	6950	6940	6940
Deprec. @ 10%/yr.		75	135	233	233	233	361	446	496	496	644	694	694	694
Net P&E		675	1215	2097	2097	2097	3249	4014	4464	4464	5796	5796	5796	5796

Figure VI-3. Estimate of Plant & Equipment for Isoenzyme Processing

Basis: 150 horses stabled year-round

for 100 horses		for 150 horses	
	Facilities (Investment)		
10K	Fencing	$ 10K	
20K	Land (20 acres @ 1K)	20K	
10K	Equipment (tractor, etc.)	10K	
10K	Accoutrements (bins, halters, etc.) @ $100/horse	15K	
180K	Barn (27,000 sq. ft. @$10/sq.ft.) (150 stalls, 12x15 ft. incl. aisle)	270K	
30K	Caretakers Quarters (1,000 sq. ft. @ $30)	30K	include office
50K	Horses (150 x $500)	75K	(with 3-4 mo. quarantine and health inspection
$310K		$430K	
	Operating Expenses		
20K	Hay (150 x $200)	30K	(20 lb/horse/day, $50/ton) (1-2 lb/ day per hundred wt, 1000 lb horse
10K	Straw (150 x $100)	15K	(10 lb/horse/day)
117K	Grain (150 x $1168)	175K	(4 lbs/horse/day, $8/100 lb)
90K	Stable men and supervision	135K	(15 men @ $9K/yr.) (1 man per 10 horses)
10K	Veterinarian	15K	(1/2 time, $30K/yr.)
90K	Overhead (100% of Labor)	135K	
$337K		$505K	

Figure VI-4. Horse Farm Estimate

Isoenzymes			Rough Estimate of No. of Personnel
Sales (dollars)	$33M		
Sales (units)	5M		
Engineering Expense	1M		20
Selling Expense	1.6M		30
Administration Expense	1.5M		50
Manufacturing Cost	15M		400
Net Annual Investment	9M		
		Total	500 personnel

Figure VI-5. Approximate Resources for Operating Year 1992

Gel Prep-Pre-Space	(1992) Annual Cost	1992 Unit Cost	Est. 1985 Unit Cost
Labor (tube filling, 60 tubes)	$ 9K		
Materials (Gels, supplies, protiens)	3K		
Overhead (100% of Labor)	9K		
	$ 21K	$ 0.02	$ 0.20
Space Processing			
Labor, Ground Ops. 10 flights	100K	.08	.50
Materials, misc.	25K	.03	.21
Services, Shuttle (see estimate)	1067K	.89	.89
Overhead (100% of Labor)	100K	.08	.50
	$ 1292K	$ 1.08	$ 2.10
Gel Processing-After Space			
Labor (see breakdown)	$ 11.1K		
Material	3.0K		
Overhead (100% of Labor)	11.1K		
	$ 25.2K	$ 0.02	$ 0.20
Horse Farm			
Labor	$ 90K		
Overhead	90K		
Material	157K		
	$ 337K	$ 0.28	$ 0.50
Antibody Prep			
Labor (see breakdown)	$ 174K		
Overhead	174K		
Material	60K		
	$ 408K	$ 0.34	$ 0.80
Packaging Kits			
Labor (see breakdown)	$ 360K		
Overhead	360K		
Material ($0.15/kit) (cap, vial, package)	180K		
	$ 900K	$ 0.75	$ 1.50
TOTAL	$ 2983K	$ 2.49	$ 5.30

Figure VI-6. Estimated Unit Manufacturing Cost
Isoenzyme Kit (Basis 1,200,000 kits/yr.)

Gel Processing Labor (post-space)

Removal Gel	1 hr.
Slice and Isolate	4 hrs.
Grind and Solubilize	8 hrs.
UV Analysis	16 hrs.
Combine fractions/freeze	8 hrs.
	37 hrs. per tube

37 hrs. x 60 tubes x $5/hr. - $11,100

Antibody Preparation (post-space)

Prep Antigen into injectable form	20 hrs.
Inject 10 horses/10 injections	80 hrs.
Bleed 10 horses/20 bleedings	160 hrs.
Separate serum	40 hrs.
Fractionate Gamma Globulin	160 hrs.
Quality Control-Gamma Globulin	40 hrs.
Freeze Dry	40 hrs.
Bind to Latex	40 hrs.
	580 hrs. per tube

580 hrs. x 60 tubes x $5/hr. = $174,000

Kit Packaging (assume automated)

1,200,000 kits 10 kits/hr. x $3/hr. = 360K
(fill and close vials, sterilize, label and package)

Figure VI-7. Labor Breakdown for Isoenzymes Kits Prep

Basis 1.2M kits/yr (1985)

	Annual Charges
Up Transport Volume (10 flts/yr.) ($0.5M^3$ x \$13,760/M^3 x 10)	\$ 68.8K
Up Transport Weight (180 kg x \$110/Kg x 10)	198.0K
Energy (0.3 kw x 156 hrs. x 10 x \$40/KWH)*	18.7K
Crew (1 man hr/day x 7 days x 10 x \$6450/hr.)	451.5K
Data Trans (None)	-
Data Proc (None)	-
Down Weight (180 kg x \$180/kg x 10)	324.0K
Ground Ops (Mech. Support) ($0.5M^3$ x \$1280 x 10)	6.4K
Gnd Ops (Elec. Support) (None)	-
Total Annual Charges	\$1067.4K

* \$40/KWH for production vs. \$1,721/KWH for R&D

Figure VI-8. Calculation of Isoenzymes Production Space Charges

Expansion of existing facilities or building of new facilities would be required for full scale production, although initial production could, and probably would be performed in available space. The horse farm for antibody growth is costed as a new purchase (investment) but since sources of similar services already exist, an option would be to arrange for antibody growth as a purchased service (expense). The kit preparation facility is envisioned as an automated process to allow throughput of millions of kits per year with relatively few operators and high quality control standards. Quality control will be an important function for the business and continuous sampling and product testing will need to be conducted to ensure a high efficacy product which meets all industry and government standards

VI.2.3 ANALYSIS OF TOTAL PRODUCTION COSTS

The selling price objective for the isoenzyme kits is to sell at the lowest possible unit price and thus to open up a product demand based on large scale diagnostic surveys. Thus all cost elements of the production sequence (Figure VI-6) require close scrutiny, and above all, detailed confirmation of their validity. The process steps are assumed to be very simple, repeatable steps, and the equipment used, including the space electrophoretic separators, are assumed to be relatively non-complex. These assumptions may not hold up under further investigation.

For lack of a better basis, the yield from each process step is presently based on obtaining 100% of a given amount from each process cycle. Perturbations in process conditions (e.g. vibration levels during space processing) could cause reduced yields and thus change the unit manufacturing cost substantially. This is especially so, due to the high multiplier which is estimated between a gram of space-separated isoenzyme and the number of kits produced. For example, a variation of one gram in space product can cause a change in production of 200,000 kits, which at $6.00 per kit, is a variation in sales of $1.2 million.

VI.3 ANALYSIS OF COST/VALUE

The isoenzyme product exhibits a very good opportunity for profitability, based on the unit price and unit cost assumptions used. The high attractiveness and uniqueness of a successful product allows flexibility in establishment of the selling price, especially in the early years, and the high volume/small space production quantity gives a relatively low unit cost.

VI.3.1 DERIVATION OF GROSS MARGIN

Gross margin, or the difference between unit manufacturing cost and selling price, for the baseline case is estimated at $6.00 - $2.50 = $3.50 per unit in 1992. Other values of margin exist in preceding years, when the unit manufacturing cost and selling price are higher. (See Section IV Cash Flow Analysis). Gross margin allows for net profit and expenses other than shop cost (i.e., R&D, engineering, selling, administration, depreciation, and interest expenses and federal income taxes). This margin (Case B) gives a net income to sales of 21 per cent in 1992.

VI.3.2 IDENTIFICATION OF SIGNIFICANT COST/VALUE ASSUMPTIONS

A key assumption in forecasting the business was that one or more isoenzymes of very high attractiveness for general diagnostic surveys would be discovered. This assumption supports the total market forecast of 50 million kits per year (1992).

A fundamental assumption, of course, is that the isoenzymes of interest do exist, that they can be isolated successfully, and that the space environment is essential to the separation process.

The R&D program assumes that the development of the gel electrophoresis separator for zero-G operation will not encounter major difficulties, and will be developed to prototype status after just a few shuttle flight experiments.

The space charges used are based on the BUS Phase III Model and are a major cost element in the forecast. Any changes in the basis for space charges will have a significant effect on the forecasted business viability, although the isoenzyme product appears to be relatively insensitive to space charges.

VI.3.3 SENSITIVITY ANALYSIS

The "present value" of the product venture (discounted at 10%) has been used as a common measure for assessing the sensitivity of the venture to the estimates used for the various cost elements. Each of the 15 parameters used in the cash flow analysis was varied ±10% and the financial forecast was calculated for each case, a total of 30 projections. The resultant present value in each case was then compared with the baseline case present value, giving the delta low (-10%) and delta high (+10%) figures as shown in Figure VI-9. The parameters with the largest changes in present value for a 10% change in estimate are thus of most interest. The high impact parameters are plotted in Figure VI-10. Assuming linearity beyond the ±10% point, a 40% reduction in unit price would cause a 4 x $3747K = $15M reduction in present value, enough to cause a negative present value for the venture. Similarly a 40% increase in the unit manufacturing cost could cause 4 x $2272K = $9M change in present value, not enough to cause a negative present value for the venture. In comparison, a much larger percentage change in the estimate of the total market or market share would be necessary to cause a negative present value. R&D costs, selling expense, administration expense, and engineering expense have a relatively small impact on the profitability of the venture.

Space charges are a major element within unit manufacturing cost (about 43%). Thus changes in the basis for assigning space charges would have a relatively significant effect on the profitability of the venture.

The above sensitivity analysis provides a rough indication of parameter sensivitity. When desired, the particular effects of parametric changes can be studied in detail by running test cases with the INVEST program.

INVEST - INTERACTIVE NEW VENTURE EXAMINATION AND SENSITIVITY TEST

SENSITIVITY ANALYSIS OF CHANGE IN PRESENT VALUE
FOR 10 PCT. CHANGE IN PARAMETER VALUE

ITEM	PARAMETER	DELTA LOW	DELTA HIGH
1	INTEREST RATE	22570.	-22570.
2	UNITS MANUFACTURED PCT.	2257537.	-2271602.
3	AVERAGE INVENTORY PCT.	62608.	-62608.
4	ENGINEERING EXPENSE PCT.	95432.	-95432.
5	SELLING EXPENSE PCT.	201117.	-201117.
6	ADMIN EXPENSE PCT.	190863.	-190863.
7	RECEIVABLES PCT.	131593.	-131593.
8	DEPRECIATION PERIOD(YRS)	-3733.	635.
9	OTHER INVESTMENT PCT.	-32898.	32898.
10	TOTAL MARKET UNITS	-1464986.	1464986.
11	MARKET SHARE PCT.	-1464986.	1464986.
12	UNIT PRICE $	-3746806.	3722523.
13	UNIT MFG'D COST $	2257537.	-2271602.
14	R + D COST $	42223.	-42223.
15	ANNUAL PLANT + EQUIP $	207377.	-207377.

PRODUCT IS ISOENZYMES CASE B
BASELINE PRESENT VALUE = 12153x61.

Figure VI-9. Isoenzymes Parameter Sensitivity Data

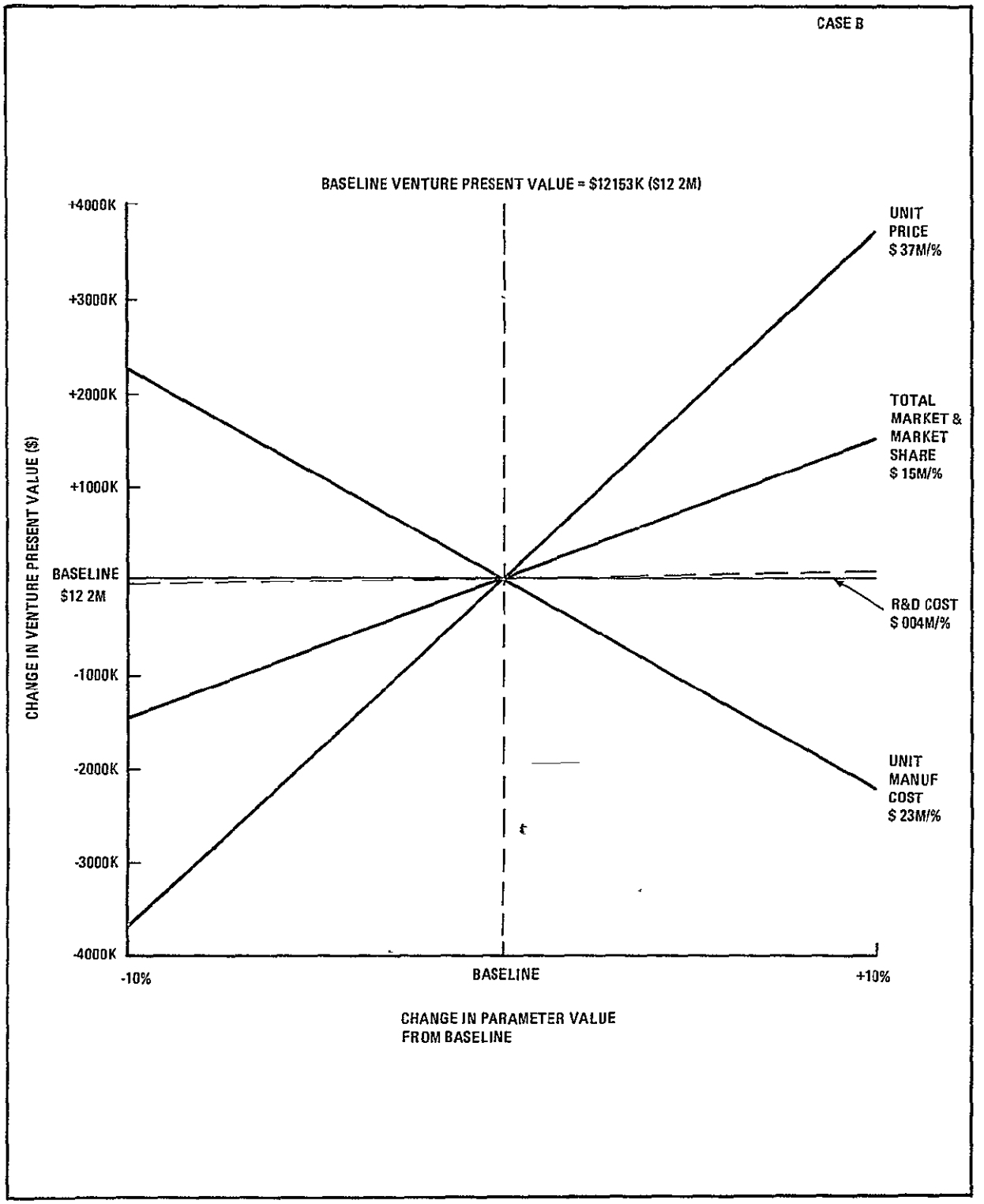

Figure VI-10. Isoenzymes Parameter Sensitivity

GENERAL ELECTRIC

Space Division /

Headquarters Valley Forge, Pennsylvania ☐ Daytona Beach, Fla ☐ Cape Kennedy, Fla
☐ Evendale, Ohio ☐ Huntsville, Ala ☐ Bay St Louis, Miss. ☐ Houston, Texas
☐ Sunnyvale, Calif ☐ Roslyn, Va ☐ Beltsville, Md